UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	MD 15-02641-PHX-DGC
Lisa Hyde and Mark Hyde, a married couple, Plaintiffs,	Phoenix, Arizona **October 2, 2018**
v.	CV 16-00893-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation, and Bard Peripheral Vascular, an Arizona corporation, Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 11 - A.M. SESSION

Official Court Reporter:
Patricia Lyons, RMR, CRR
Sandra Day O'Connor U.S. Courthouse, Ste. 312
401 West Washington Street, SPC 41
Phoenix, Arizona 85003-2150
(602) 322-7257

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

A P P E A R A N C E S

For the Plaintiffs:

Lopez McHugh
By: **RAMON R. LOPEZ**, ESQ.
100 Bayview Circle, Suite 5600
Newport Beach, CA 92660

Gallagher & Kennedy
By: **MARK S. O'CONNOR**, ESQ.
By: **PAUL L. STOLLER**, ESQ.
2575 East Camelback Road, Suite 1100
Phoenix, AZ 85016

Heaviside Reed Zaic
By: **JULIA REED ZAIC**, ESQ.
By: **LAURA E. SMITH**, ESQ.
312 Broadway, Ste. 203
Laguna Beach, CA 92651

Goldenberg Law PLLC
By: **STUART GOLDENBERG**, ESQ.
By: **MARLENE GOLDENBERG**, ESQ.
800 LaSalle Ave., Ste. 2150
Minneapolis, MN 55402

Lopez McHugh, LLP
By: **JOSHUA MANKOFF**, ESQ.
1 International Plaza, #550
PMB-059
Philadelphia, PA 19113

For the Defendants:

Nelson Mullins Riley & Scarborough.
BY: **JAMES F. ROGERS**, ESQ.
1320 Main St.
Columbia, SC 29201

Snell & Wilmer
By: **JAMES R. CONDO**, ESQ.
400 East Van Buren
Phoenix, AZ 85004

A P P E A R A N C E S (CONTINUED)

For the Defendants:

Nelson Mullins Riley & Scarborough
By: **RICHARD B. NORTH, JR.**, ESQ.
By: **MATTHEW B. LERNER**, ESQ.
By: **ELIZABETH C. HELM**, ESQ.
201 17th Street NW, Suite 1700
Atlanta, GA 30363

C.R Bard, Inc.
Associate General Counsel, Litigation
By: **CANDACE CAMARATA**, ESQ.
730 Central Avenue
Murray Hill, New Jersey 07974

I N D E X

EXAMINATION

EXHIBITS

(Index of Exhibits Continued)

EXHIBITS

(Index of Exhibits Continued)

EXHIBITS

P R O C E E D I N G S

(Proceedings resumed in open court outside the presence of the jury.)

08:31:01 THE COURT: Thank you. Please be seated.

Morning, everybody.

EVERYBODY: Morning, Your Honor.

THE COURT: Counsel, later this morning we will file the order on the Rule 50 motion. I am granting it on the
08:31:32 future damages on possible arrhythmias and possibility of a defibrillator. My conclusion is that the evidence isn't sufficient under Wisconsin law for that claim.

I am denying it on the loss of consortium claim, the strict product liability claim, and the punitive damages
08:31:54 claim. And that's all explained in an order that will be filed later this morning.

So one of the things to think about for purposes of the jury instructions that we'll talk about at the end of the day is how we clarify what damages are available for the jury
08:32:10 to award.

Are there matters plaintiffs' counsel would like to raise before we get started this morning?

MR. O'CONNOR: Let me just --

MS. REED ZAIC: You can't move it until court.

08:32:25 MR. O'CONNOR: I'm just letting him know.

08:32:27 We'll move an exhibit in before we start -- well, at the appropriate time, we have an exhibit we agreed to, 992.

THE COURT: Okay.

MR. ROGERS: Nothing from defendants, Your Honor.

08:32:35 And I think this video's only probably got few more minutes left. And if that's a good time, they can certainly move the document into evidence at that point.

THE COURT: Okay. And then what other witnesses will you be calling today?

08:32:48 MS. HELM: Your Honor, I'll answer. Our first witness is going to be Dr. Donna-Bea Tillman and then she'll be followed by Dr. Paul Briant, and there may be a short video in between.

THE COURT: And then what?

08:33:04 MS. HELM: And then Mr. Van Vleet.

THE COURT: Okay. I don't -- I don't think there were motions, *Daubert* motions, filed on either of those; is that right?

MS. HELM: That's right, Your Honor.

08:33:25 MR. ROGERS: Correct.

THE COURT: Okay. How long do you think that evidence will go?

MS. HELM: We anticipate -- we have Mr. Randall also available at the end of the day if we don't finish today. We

08:33:39 do have a couple of short videos in between live witnesses.

08:33:43 We're not going to put them all at the end of the day.

THE COURT: So you're not going to rest today?

MS. HELM: We don't think so.

THE COURT: Okay.

08:33:50 Okay, we'll come back at 9 o'clock. Go ahead about your business.

MR. ROGERS: Thank you, Your Honor.

(Recess taken from 8:34 to 9:00. Proceedings resumed in open court with the jury present.)

09:01:28 THE COURT: Thank you. Please be seated.

Good morning, ladies and gentlemen.

JURORS: Good morning.

THE COURT: Hope you're not too wet. Thank you for being here.

09:01:43 We're going to start this morning where we left off, with the video testimony of Dr. DeFord.

You may proceed.

(Video testimony of Dr. DeFord concluded.)

MR. ROGERS: Your Honor, at this time defendants call 09:08:39 Dr. Donna-Bea Tillman.

MR. O'CONNOR: Can I move this into evidence?

MR. ROGERS: Oh. Yeah. I'm sorry. Forgot about the housekeeping matter.

MR. O'CONNOR: Your Honor, we were going to move one 09:08:50 exhibit into evidence that I believe is stipulated to. That

would be Exhibit 992.

MR. ROGERS: No objection, Your Honor.

THE COURT: All right. 992 is admitted.

(Exhibit 992 admitted.)

THE COURTROOM DEPUTY: If you'll please come forward and raise your right hand.

DONNA-BEA TILLMAN, Ph.D,

called as a witness herein, after having been first duly sworn or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N

BY MR. ROGERS:

Q Good morning, Dr. Tillman.

A Good morning.

Q How are you?

A I'm very well, thank you.

Q Good. Can you tell the ladies and gentlemen of the jury what your profession is.

A Yes. I'm a regulatory affairs professional and I'm an engineer by training.

Q Can you tell us where you live?

A I live in Columbia, Maryland.

Q And are you married?

A Yes, I am.

Q How about your educational background, can you describe that for the jurors?

09:10:20 A Sure. I have an undergraduate degree in engineering and biology, and then I went to graduate school at Johns Hopkins and I got a Ph.D in biomedical engineering. When I was at the FDA I went back and got a masters in public administration.

09:10:38 Q You mentioned you were at FDA. I'm going to walk through your career. When you first got out of school, can you tell the jurors what your first job was?

A Yes. When I finished my Ph.D I went to work for the US Consumer Product Safety Commission. That's a branch of the

09:10:57 federal government that not a lot of people know about, and their responsibility is to ensure the safety of consumer products.

Q What were the years you were at the Consumer Product Safety Commission?

09:11:10 A I was there roughly from 1992 to 1994.

Q And so thereafter did you ultimately go to FDA?

A Yes, I did.

Q And what year did you begin working at FDA?

A I believe it was 1994.

09:11:23 Q And so what was your first position when you started working at FDA?

A So I started at FDA as a reviewer. So which is the sort of introductory position of people who actually do reviews of premarket submissions.

09:11:39 Q And as a reviewer, what would you -- what would your job

09:11:42 duties be?
A So I would be responsible for reviewing 510(k)s and PMAs and IDEs and other regulatory submissions. I would look at the submissions and evaluate the quality of the information in
09:11:57 there to determine whether it met FDA's regulatory requirements. So that was mostly what I did.
Q And approximately how many years did you spend as a reviewer?
A I was a reviewer for three years.
09:12:12 Q Then thereafter did you move to a different position?
A Yes. I decided it was time to look at other career options, and so I applied for and got a position as a branch chief. So I was basically promoted to a sort of first level of management within FDA.
09:12:28 Q So when you shifted from being a reviewer to branch chief, you were still at FDA?
A I was.
Q And I think you said this, but was that considered a promotion?
09:12:38 A Yes, it was.
Q What were your job duties as a branch chief?
A That was a first level management position. So I had 14 to 16 scientists and clinicians that worked for me and they would review submissions, and my job was to ensure the
09:12:55 consistency and the quality of the work done by the reviewers

09:12:59 in my branch and to sign off on their review recommendations.
Q And what was the branch you were in charge of?
A So it was the -- it changed a little bit over time, but it was the Pacing Branch and then the Cardiac Electrophysiology
09:13:17 Branch. These are branches involved with the review of cardiovascular devices.
Q And did you again receive a promotion within FDA?
A Yes. After a couple of years in that position I was promoted to be the deputy director for the Division of
09:13:35 Cardiovascular Devices.
Q And what were your job duties in that position?
A So as the deputy division director, I had three branches that reported to me and my job there was to ensure that, once again, the consistency and quality of the science and the
09:13:53 regulatory work that went on in those three branches, to make sure that our division was following appropriate regulatory policy, and then basic organizational management functions.
Q So in that position, approximately how many people would you have that would be reporting to you?
09:14:11 A So I had three branch chiefs that reported to me, and then they had reviewers reporting to them. So roughly 30 to 40 people reported to me in that position.
Q And did you then move to a different position?
A Yes. So then after a couple of years in that position I
09:14:29 once again got promoted to be the deputy director for

technology and review policy for the Office of Device Evaluation.

Q Can you tell us what the Office of Device Evaluation is?

A Yeah. So the center at FDA that's responsible for medical devices is called the Center for Devices and Radiological Health, and it has a number of offices within it. And one of those, the office that's responsible for premarket review of submissions, is Office of Device Evaluation. So at this point in time I had been promoted to be the deputy office director for that office.

Q And is it okay with you if we refer to the Office of Device Evaluations as ODE?

A Yeah, that's what most people call it.

Q Okay. Thank you.

And so ultimately did you move to a different position within FDA?

A Yes. So I had -- I was the deputy director for about six months when I actually got the opportunity to become the director of the Office of Device Evaluation. So I was promoted from the deputy to being the director of the Office of Device Evaluation in I think it was 2004.

Q And how long did you hold that position?

A So I had that position for six years.

Q And what would your job responsibilities have been as the director of the ODE?

09:15:47 A So in that position I was responsible for overseeing the premarket review program for all medical devices except for the In Vitro Diagnostic Devices, and that included things like developing policy and procedures about how we would review
09:16:04 submissions, reviewing and being responsible for signing off on some of the more novel and first-of-a-kind devices for the novel products. Organizational management. You know, functions, managing a large organization, people stuff. But mostly it was sort of -- it was to make sure that we had a
09:16:24 consistent review policy across the office.

Q And how many people would have been, to use -- I'm not coming up with a better word right now. How many people would have been under you in that position?

A So my office at that time was about 350 scientists,
09:16:40 engineers, and medical officers.

Q So how many years total were you at FDA?

A I was at FDA for 17 years.

Q And when you were the office director for the ODE, approximately how many premarket submissions were you involved
09:16:58 with for medical devices?

A So during my time at FDA, I was involved with probably thousands of submissions. When I was the director of ODE, I was only involved with the sort of higher level first-of-a-kind submissions. The first drug-eluting stent,
09:17:19 reintroduction of silicone gel breast implants, first

09:17:26 pacemaker for heart failure. So I was involved in those submissions. And then for certain kinds of more novel 510(k) submissions.

Q Was one of your job responsibilities when you were the 09:17:37 director of ODE to actually sign off on clearance letters for 510(k) applications?

A Yes, it was.

Q And approximately how many letters did you sign off on when you were in that position?

09:17:49 A So when I was in the -- when I was office director, I probably signed off on maybe 20 or 30. Where I ended up signing off on more 510(k)s was back when I was in cardiovascular. When I was deputy director of cardiovascular, I signed off on all of the 510(k)s that went through the 09:18:11 cardiovascular division in those three years. During that time, probably several hundred 510(k)s.

Q I think you told us you left FDA sometime in 2010; is that right?

A Yes.

09:18:21 Q And so where did you go after that?

A I went to work for Microsoft. One of my areas of interest is medical device software and when software is regulated as a medical device. Microsoft was interested in getting into the medical device space and so I went there and helped them 09:18:39 establish a FDA regulatory program for their medical device

09:18:43 software.
Q How long were you with Microsoft?
A I think I was there about two and a half years.
Q And what led you to leave Microsoft?
09:18:51 A So they decided that they were going to engage in -- merge into a joint venture with another company and they wanted me to move to Seattle, which it was not going to be a good thing for me to do due to some family obligations, and so that's why I decided to leave.
09:19:08 Q So have you been, I guess what I would call sort of the greater Washington, D.C. area your entire career?
A Yeah. I came up to go to grad school to go to Hopkins in '85 and I never left. Met my husband, got married, had a house, got a bunch of dogs. I've lived there since then.
09:19:28 Q And so, Dr. Tillman, who do you work for now?
A I work for a company called Biologics Consulting Group.
Q What do you for that company?
A So Biologics Consulting consists of people like myself who worked at FDA or people from the medical device and
09:19:45 pharmaceutical industry, and we help companies, startups or large companies sometimes, figure out what kind of data do they need in order to support marketing applications for FDA, and we help them basically navigate the FDA review process.
Q Dr. Tillman, while you were at FDA, were you directly
09:20:06 involved with any applications regarding IVC filters?

09:20:09 A I was.
Q Let me ask you this: You did -- I'm sorry, I'm kind of bouncing around on you.
You told us you're working for a consulting company
09:20:22 now --
A Yes.
Q -- right?
And so as part of that job, do you do some litigation consulting?
09:20:30 A I do. Roughly 15 to 20 percent of the work I do is litigation consulting work. But the vast majority of what I do is what I would call traditional regulatory consulting.
Q And are you charging for your time today?
A Yes. I am an employee of a company, so I get paid a
09:20:48 salary, but my company clearly bills for my time.
Q And what is the rate at which your company is billing for your time?
A So my company bills $500 an hour for my time when I'm involved with litigation work.
09:21:01 Q In addition to consulting with Bard on the matter we're here for today, have you also worked with Bard in regard to other products besides IVC filters?
A Yes, sir, I have.
Q And what is that, please?
09:21:15 A So I'm also involved in Bard's litigation for the

09:21:19 transvaginal mesh products.

Q And, Dr. Tillman, is it fair to say you have spent the majority of your career working in areas of FDA regulation of medical devices?

09:21:32 A Yes, that's what I've done for the vast majority of my career.

Q And will you be offering opinions about the regulatory processes for the Bard IVC filters for the jury today?

A Yes, I will.

09:21:44 Q Okay. Let me start you off, I guess, with some more general things.

You know, we have heard some evidence in this case about there being different classes of medical devices, but can you describe that generally.

09:21:58 A Sure.

Because medical devices are so varied, you have things ranging from tongue depressors and toothbrushes all the way up to pacemakers and heart valves, the regulation of medical devices is risk based. So FDA basically classifies

09:22:15 medical devices into three categories depending on the level of risk.

The Class I devices are the lowest risk devices. Things like toothbrushes and tongue depressors, manual surgical instruments. And those devices generally do not

09:22:32 require any premarket submission to FDA.

09:22:36 The second group of devices, which is really the largest group, are the Class II devices. And those are devices that are more moderate risk where FDA understands the risks and the benefits of these devices and those devices 09:22:51 generally require companies to submit something called a 510(k), which I think you guys have heard about, premarket notification to FDA, and FDA has to review that information and clear the 510(k) before those devices can be sold.

And then the third class of devices are the Class III 09:23:10 devices. Those are the most risky or the most novel medical devices. The highest risk. And in order to sell a class III device, most Class III devices, a company has to submit something called a PMA to FDA and demonstrate that there's a reasonable assurance of safety and effectiveness.

09:23:30 So that's the kind of regulatory paradigm that exists for medical devices.

Q All right. Let me followup with you about the PMA. What does that stand for?

A So a PMA is a premarket approval application.

09:23:43 Q And so if a device goes through the PMA process, what is the regulatory standard FDA will apply to that device?

A So in order for FDA to approve a PMA, it must find that there is a reasonable assurance of safety and effectiveness.

Q And is that what we call an approval if FDA gives the 09:24:08 thumbs up to one of those devices?

09:24:10 A Yes. When a PMA -- when FDA finishes it's review of a PMA we say it is approved.

Q Can you compare that process to the process called 510(k) process?

09:24:22 A Yes. So the 510(k) process is also a process that involves an assessment of safety and effectiveness, but the finding FDA makes is that the device is substantially equivalent to another device.

And so while there is a consideration of safety and

09:24:40 effectiveness, it's not a finding of a reasonable assurance of safety and effectiveness in the same way a PMA is.

Q So when the device goes through a 510(k) process and FDA allows that device onto the market, how do we refer to that? What is it known as?

09:24:57 A So we say the 510(k) is cleared. Not that it's approved.

Q And of these two different types of processes to enter a medical device into the market, can you describe for the jury approximately what percentages of devices go through the PMA process versus how many go through the 510(k) process?

09:25:22 A So the vast majority of medical devices out there have gone through the 510(k) process.

FDA receives roughly 3- to 4,000 new 510(k) submissions every year and they receive, depending on the year, anywhere from 30 to 50 PMA submissions. So the vast

09:25:41 majority of the devices you might encounter when you go to

09:25:45 your doctor's office or the hospital are devices that are cleared through the 510(k) process.

Q And the IVC filters that we're talking about today, the G2X filter and Eclipse filter, are those filters -- do they go 09:25:58 through the 510(k) process?

A Yes, they do.

Q So let's talk about that in a little more detail. You described for us the substantial equivalence process. Or that being the standard at which those devices are measured.

09:26:10 Can you give the jury more information about what that standard means.

A Yes.

So it's a little bit complicated, so bear with me.

So substantial equivalence is about a comparison to 09:26:24 something we call a predicate. A predicate is another device that's already legally marketed for the same intended use.

So if you've developed a new medical device and it's Class II and it's subject to 510(k), you would identify some other device that is already out there that has the same 09:26:43 intended use as your device, and you would say that's going to be my predicate.

And then once you've determined or demonstrated that the device has the same intended use, then the next question is how do the technological characteristics of your device 09:27:00 compare to the other device you're comparing to? So does your

09:27:03 device have the same technological characteristics? Does it have a different design? Does it use a different energy? If it does, then those are different technological characteristics.

09:27:13 And if it has different technological characteristics, then the next question is do those differences raise different kinds of questions? Are the kinds of risks and things that we have to consider so different from your device and the other device that they can't really be

09:27:31 compared? If that's the case, then you need a PMA. If the technological characteristics are different but they're not so different you can't do a meaningful comparison, then what FDA does is it looks at data and it says, okay, you've got this device, it's got the same intended use. Yeah, it looks a

09:27:50 little different, has different technological characteristics, but if you can provide data to show that the performance demonstrates that the safety and effectiveness are comparable to that of the predicate device, then FDA can determine that it's substantially equivalent.

09:28:06 Q Dr. Tillman, the jury has heard at various times during the trial about FDA guidance documents. But can you remind us what those are?

A Yes. So there is -- there is statute, which is the laws that Congress passes. And then FDA implements things called

09:28:22 regulations, which is where FDA takes the statute and develops

09:28:27 regulations about how it's going to -- how it's going to apply that statute. And then underneath that are guidance documents. These are documents that FDA writes to help people understand its review programs.

09:28:40 The same way that the Internal Revenue Service publishes tax guidance where if you've got a question about a particular tax matter, you can go look it up.

FDA writes guidance documents to help companies understand what its requirements and regulations are.

09:28:54 Q Has the FDA issued a guidance document on the substantial equivalence process?

A Yes. FDA has issued many guidance documents on the substantial equivalence process.

Q And are you familiar with those guidance documents?

09:29:09 A I'm deeply familiar with them.

MR. ROGERS: Scott, can we pull up Exhibit 7758, please.

BY MR. ROGERS:

Q And, Dr. Tillman, can you see on your screen the document?

09:29:20 A Yes, I can.

Q What is the title of that document?

A So The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications.

MR. ROGERS: Your Honor, I move this into evidence.

09:29:33 MR. LOPEZ: I object. I'm going to object to it as a

09:29:40 2014 document, which is a time period not relevant to this case.

THE COURT: I think additional foundation's needed on that point.

09:29:49 MR. ROGERS: Thank you, Your Honor.

BY MR. ROGERS:

Q Dr. Tillman, have you reviewed this guidance document?

A Yes, I have.

Q And was it in place when you were at FDA?

09:29:57 A This particular version of this guidance document was not. This is a newer version of a document that was established back in the 1990s.

Q And based on your review of this guidance document, are the standards that this document describes consistent with the

09:30:15 standards that were applied when you were at FDA regarding substantial equivalence?

A Yes. The basic principles in this guidance document, the concepts of intended use, different technological characteristics, when is a question a new type of question,

09:30:30 that basic -- those concepts and how FDA interprets those haven't changed in the 30-some years since the program was put in place. This guidance provides a sort of more detailed explanation of those, but it reflects a review policy and an approach that really has existed since the 510(k) program

09:30:49 first came into being.

09:30:52 Q Does this document reflect FDA standards regarding substantial equivalence that would have existed in 2009 and 2010?

A Absolutely.

09:31:02 MR. ROGERS: Your Honor, I move this document in evidence.

MR. LOPEZ: I'm still going to object. She said more detail than before. This is a 2014 document.

THE COURT: All right. That's a relevancy objection,

09:31:11 I assume.

MR. LOPEZ: Yes, Your Honor.

THE COURT: I'm going to overrule it on relevancy grounds. You certainly can go into those differences on cross-examination.

09:31:19 MR. LOPEZ: Thank you, Your Honor.

THE COURT: Exhibit 7758 is admitted.

(Exhibit 7758 admitted.)

MR. ROGERS: Your Honor, may we publish?

THE COURT: Yes.

09:31:30 BY MR. ROGERS:

Q So, Dr. Tillman, again, just to orient the jury, if you would, can you tell us what this guidance document is intended to do.

A So this guidance document is intended to help both FDA

09:31:40 reviewers and medical device companies understand what they

09:31:44 need to do, what information needs to be provided in a 510(k) submission, and what are the standards and criteria FDA uses for determining when a device is substantially equivalent.

MR. ROGERS: Okay. Can we go to page 9, please.

09:32:01 And can we pull out that portion that says "The Statutory Standard," please.

BY MR. ROGERS:

Q And, Dr. Tillman, can you explain for the jury what this is? What are we seeing here?

09:32:15 A So this is basically going over the same thing we just talked about a few minutes ago, which is the 510(k) standard is one of substantial equivalence whereas the PMA standard is one of reasonable assurance of safety and effectiveness. And so FDA is pointing out that there's a difference in those

09:32:35 standards but that, however, the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review.

So what FDA's saying here, in my opinion, is that even though the standard is not the same, in both cases FDA is

09:32:51 looking at safety and effectiveness.

Q And does substantial equivalence mean that a device, new device that's being proposed to FDA, must share the same design characteristics as the predicate device?

A No. In fact, as I was saying a little bit ago, when you

09:33:09 have a new device it can have different technological

09:33:12 characteristics and still be found substantially equivalent.
Q And what are the types of data a manufacturer needs to submit to FDA to show FDA that a new device is substantially equivalent to a predicate device?
09:33:27 A So the types of data in a 510(k) depends on the type of device. If it's a device like a filter, FDA would be looking at things like the materials, are they bio compatible. If the device is sterile they want to know, is it sterile. They want to understand what are the mechanical properties of it? Is it
09:33:46 strong enough to withstand the forces it's going to be subjected to? If the device has software, there's software documentation. If the device is electrical, FDA asks companies show it is electrically safe.

The types of testing and data in a 510(k) is very
09:34:02 much dependent on the particular type of device.
Q Does substantial equivalence mean a proposed device must have the exact same benefits profile as a predicate device?
A No, it does not have to have the same benefits.
Q And does substantial equivalence mean that a proposed
09:34:19 device has to have the exact same risks as a predicate device?
A No, it does not.
Q Have you seen instances where the FDA has cleared a new device even though it may have a different type of complication than the predicate device?
09:34:34 A Yes, I have certainly seen situations where FDA looks at

09:34:38 different risk/benefit profiles when it clears a device.

MR. ROGERS: All right. Scott, would you mind taking that down, please.

And can you pull up Exhibit 7753.

09:34:49 BY MR. ROGERS:

Q And, Dr. Tillman, can you see this on your screen?

A Yes, I can.

Q And what do we see here?

A So this is another FDA guidance about 510(k) and this one

09:35:03 is about benefit/risk factors to consider when determining substantial equivalence in premarket notifications with different technological characteristics.

Q And when was this guidance document issued?

A So this document was issued in 2014.

09:35:20 Q So this issued after you were at FDA?

A Yes, it was.

Q And have you reviewed this guidance document?

A I have.

Q Are the general standards that this guidance document

09:35:32 describes consistent with the standards that applied when you were at FDA?

A Yes. This guidance document was written in order to put down on paper, basically, what FDA had been doing for the past 20 or so years so that companies and FDA staff who review

09:35:50 510(k)s could better understand how to think about benefit and

09:35:55 risk in the context of a 510(k) submission.
Q And were the standards that are described in this guidance document, were they being applied in 2009 and 2010 at FDA?
A Yes, they were.
09:36:10 MR. ROGERS: Your Honor, I move this document into evidence.
MR. LOPEZ: Objection. Relevance and foundation. It's a draft document.
THE COURT: I think you need to address the draft
09:36:19 issue and foundation.
MR. ROGERS: Thank you, Your Honor.
BY MR. ROGERS:
Q Dr. Tillman, as we just heard, is this a draft guidance?
A Yes, it is.
09:36:27 Q Can you describe for the jury the process that guidance documents are created by FDA.
A Yes. So when FDA develops a guidance document it first puts out a draft and that draft is published and then people are able to comment on that draft and then FDA will issue a
09:36:45 final guidance document.
In a case like this where you've got a guidance -- this guidance did not exist before 2014. Even though it is a draft guidance document, it still reflects what FDA was doing and had been thinking. So the fact that it is draft doesn't
09:37:03 really change the fact that it reflects what FDA had been

09:37:08 thinking for many years before it was published.

Q And when FDA publishes draft guidance for the industry, do those sometimes stay in draft for several years?

A Yes. In fact, this draft -- this device has been draft 09:37:27 since 2014 and it was -- only actually recently has been issued in final.

Q And does the fact it is a draft guidance reduce its importance as far as the information it is providing to industry?

09:37:45 A You know, I would say that because it's a draft guidance it can't be enforced by FDA. Although I would say that guidances are never required, so it's kind of funny to talk about them being enforced.

The fact it's draft, though, doesn't change the fact 09:38:01 that it still reflects how FDA thinks about risk/benefit.

And so because this guidance is really more about explaining how FDA thinks about risk/benefit versus telling companies what to do, I think the fact it's a draft doesn't really change the fact that it explains what FDA is thinking 09:38:24 about.

MR. ROGERS: Your Honor, I move this document into evidence.

MR. LOPEZ: Same objection. Foundation.

THE COURT: All right. Objection is overruled. 09:38:30 Exhibit 7753 is admitted.

09:38:34 (Exhibit 7753 admitted.)

MR. ROGERS: May we display?

THE COURT: You may.

BY MR. ROGERS:

09:38:39 Q All right. And so, again, to orient the jurors, Dr. Tillman, what was the purpose behind this particular guidance document? What information was it intended to convey?

A I think it's intended to convey how do you think about 09:38:52 risk and benefit when you have devices that have different technological characteristics.

So if I have a device with this design and it has a set of risks and benefits and I have another device I'm comparing it to with another design and different risks and 09:39:07 benefits, how do I compare those two devices and show that the risk/benefits are the same for purposes of substantial equivalence.

MR. ROGERS: Can we go to page 7 of the document, please.

09:39:19 Under that section, the big section called Scope down at the bottom, can you pull that out, please.

BY MR. ROGERS:

Q Okay. Dr. Tillman, can you describe for us what we're seeing here?

09:39:32 A So this is talking about the scope of the guidance. And,

09:39:35 once again, it's reminding the reader that new device doesn't have to be identical to a predicate device in order to be found substantially equivalent.

Q Is that consistent with your understanding and opinions as a regulatory expert?

09:39:52 A Yes, and also consistent, frankly, with how the regulations sort of define and characterize substantial equivalence. Because the regulations clearly say that a device can have new technological characteristics and still be substantially equivalent.

09:40:08 MR. ROGERS: Can you pull that box down and go to the next page, please.

And can you pull out the section called Benefit and Risk Factors.

09:40:17 BY MR. ROGERS:

Q Okay. Dr. Tillman, can you describe for us what this paragraph is about?

A So in this paragraph, FDA is noting that a device can be found substantially equivalent even if it has different

09:40:36 benefits and risks. It talks about the fact -- and the whole guidance, in fact, talks about how does FDA look at benefits and risks, how does it attempt to quantify them, and how does it use that information to determine that a new device has a equivalent benefit/risk profile to a predicate device.

09:41:00 MR. ROGERS: Scott, would you mind taking that down

09:41:01 and going to the next page, please.

And can you pull out the section called Increased Risk/increased Benefit.

BY MR. ROGERS:

09:41:10 Q And, Dr. Tillman, do you see that on your screen?

A Yes, I do.

Q Can you describe for the jury what this paragraph is about and what FDA is conveying in this paragraph?

MR. LOPEZ: This is not in her report.

09:41:23 THE COURT: Is this in her report?

MR. ROGERS: Yes, Your Honor. Page 40, top of the page.

MR. LOPEZ: Not the entirety of it, Your Honor.

THE COURT: All right, let me look at it.

09:42:13 The report only quotes language, it doesn't go into an explanation of it, so I think you can have her --

MR. ROGERS: We'll --

THE COURT: You can't have her explain it since it's not in the report.

09:42:26 MR. ROGERS: Okay. Thank you, Your Honor.

MR. LOPEZ: It's being displayed to the jury right now, can we take it down.

THE COURT: Pardon?

MR. LOPEZ: It's being displayed to the jury right

09:42:30 now. Can we take it down.

09:42:30 THE COURT: It's in evidence.

MR. LOPEZ: I know. Okay.

MR. ROGERS: Scott, if you could, could you pull out the just the first sentence of that paragraph, please.

09:42:40 THE COURT: Well, let me make -- it's in evidence and this portion, the first sentence, is quoted in the report. That's why I think it's within the scope.

BY MR. ROGERS:

Q Dr. Tillman, what does this sentence say? I mean can you

09:42:58 just read it for us, please.

A Yes. It says, "If the risks associated with the new device increase as compared to the predicate device, FDA may still determine that the new device is SE to the predicate device if, for example, FDA finds from a review of the new

09:43:16 device's performance data that there are also increased benefits with the new device as compared to the predicate device."

Q Okay. Thank you.

MR. ROGERS: You can take that down.

09:43:27 And you can take the document down.

BY MR. ROGERS:

Q So, Dr. Tillman, who ultimately decides whether a predicate device is appropriate for clearance in comparison to an existing predicate device?

09:43:42 A So FDA makes the determination that the predicate device

09:43:45 is appropriate.
Q And when the FDA is making that determination, does the FDA sometimes have more information than the manufacturer who is submitting the application?
09:43:55 A Yes, it does.
Q And so how does FDA use that information that it has, if it uses it at all?
A So FDA uses any information it has available to it in making these decisions. It may consider data from the
09:44:11 post-market setting, it may consider data that it knows from other submissions that it's reviewed. All of that information is considered by the agency when it makes these decisions.
Q And who make the decision whether a device raises any new or different types of safety or efficacy questions?
09:44:30 MR. LOPEZ: Objection. Just vague and ambiguous, Your Honor, as to time.
MR. ROGERS: I can ask for a specific time.
THE COURT: Please ask for a time.
BY MR. ROGERS:
09:44:41 Q Dr. Tillman, in 2009 and 2010 who makes the decision about whether or not a device raises new types of safety and efficacy questions?
A FDA makes that decision.
Q And when does FDA make the determination whether a device
09:44:56 is substantially equivalent to a predicate device?

09:44:59 A So a company submits a 510(k) submission, FDA reviews it, and then FDA makes a determination that the device is substantially equivalent and then sends a letter to the company saying that it has found it as substantially
09:45:13 equivalent.

Q And were you involved in those types of decisions when you were at FDA?

A I have been involved in those decisions at FDA and as a consultant as well.

09:45:23 Q And once FDA has determined that a new device should be cleared as substantially equivalent to a predicate device, what does FDA do to continue a review of substantial equivalence after the new device is on the market?

A So there is not a continued assessment of substantial
09:45:43 equivalence. That is a finding that FDA makes and then that is -- that's called a premarket review. And then from then on FDA has post-market authorities that it can use, such as assessing adverse events or looking at how devices are performing in the post-market setting. But it doesn't
09:46:04 continually evaluate substantial equivalence.

Q And how does FDA monitor or evaluate a device in the post-market setting after a device has been introduced into the marketplace?

A So I already mentioned there is a mandatory adverse event
09:46:19 reporting system called the MDR system. FDA has also

09:46:25 authorities to monitor companies' quality systems. It goes and inspects companies. FDA has the ability to look at information, statements, companies are making about their products and making sure that they are not misleading.

09:46:41 So FDA has a number of post-market authorities that it can apply.

Q If there is a -- what I would call a chain of clearances, and by that I mean if you have a device and a new device is cleared in comparison to an original device and then another

09:46:59 device is cleared in comparison to the second device, is there any connection between the clearance of the third device versus the original device?

MR. LOPEZ: Your Honor, I'm going to object. This is not in her report.

09:47:14 MR. ROGERS: Your Honor, deposition page 330, lines 8 to 12.

MR. LOPEZ: What was the page again? I missed the page.

MR. ROGERS: 330.

09:47:36 MR. LOPEZ: 8 to 12.

THE COURT: Objection's overruled.

BY MR. ROGERS:

Q Dr. Tillman, do you recall the question.

A Yes, I can.

09:47:55 So substantial equivalence is a comparison of a

09:47:59 device to a predicate device. And there is not a requirement that you trace that equivalence all the way back to the first device in the chain. Because if you think about it, we've talked about a device can have different technological
09:48:14 characteristics and different risk/benefits compared to its predicate. And that might happen here. And then if that happened before, you end up with devices that sometimes can be very different from the original predicate but are still substantially equivalent to the first predicate.

09:48:32 Q All right. Let me shift your -- shift gears and talk a little bit about IVC filters in particular.

What class of devices do IVC filters fall in?

A IVC filters are currently Class II devices.

Q Were IVC filters always Class II devices?

09:48:52 A No. Originally IVC filters were actually what we call pre-amendment Class III devices.

Q And generally speaking, when the FDA -- well, let me back up for a second.

Can the FDA from time to time do what is called down
09:49:06 classifying a device?

A Yes, it can.

Q What is that?

A So based on information that is available, as we learn more about devices, sometimes FDA may decide that the
09:49:19 classification is no longer appropriate and it may decide that

09:49:24 a device was in Class III can now be appropriately regulated in a lower class. That is what we referred to as down classification. It was Class III and now it's Class II.

Q And did that process happen with IVC filters?

09:49:39 A Yes, it did.

Q And as part of FDA's decision to down classify IVC filters from Class III to Class II, did FDA identify any special controls for IVC filters?

A Yes. In deciding to down classify the device, the IVC

09:49:59 filters, the FDA determined it understood what the risks and benefits were and that it could identify how to mitigate those risks.

So we've got these risks. What can we do to make sure we can mitigate them? And then that information then

09:50:13 gets put into a guidance document called a Special Control Guidance Document. And FDA created Special Control Guidance Document for IVC filters when they down classified them from Class III to Class II.

Q And just in general, can you describe for us what a

09:50:31 special control is.

A So a special control is a -- it is something that a company will do in order to address a risk. So if I have a risk -- for example, if the risk is that the material is not compatible with the human body, then a special control for

09:50:54 that might be that the company needs to demonstrate that the

09:50:57 device complies with a standard for biocompatibility testing and that they've done testing to show the device is safe for contact with human tissue.

So special controls are things that have to be done

09:51:12 in order to show that a risk has been mitigated.

MR. ROGERS: Can we pull up Exhibit 5126, please.

And, Your Honor, I believe this is in evidence.

THE COURTROOM DEPUTY: Yes.

THE COURT: It is.

09:51:30 MR. ROGERS: May we publish?

THE COURT: You may.

BY MR. ROGERS:

Q Dr. Tillman, is this the guidance that FDA issued for IVC filters?

09:51:39 A Yes, it is.

Q And is it a common practice for FDA to issue a guidance that relates to a particular type of device?

A So, actually, the vast majority of devices do not have device-specific guidance documents. There are cross-cutting

09:51:59 guidance documents that apply to these devices, like for biocompatibility or software or electrical safety, but the vast majority of devices do not have an actual specific device-specific guidance document.

Q If FDA issues a device-specific guidance document like

09:52:19 this one does FDA expect manufacturers, when they submit

09:52:23 applications, to follow the guidance document?
A Yes. Even though guidances are supposed to only be recommendations, FDA very much expects companies to comply with the recommendations in the guidance or to have a very
09:52:38 good reason for why they did not.
Q And how does a guidance like this help a manufacturer like Bard submit a 510(k) for an IVC filter?
A The benefit of a guidance like this is both FDA and the manufacturer understand what is the data that FDA expects to
09:52:57 see in this submission. So it helps the manufacturer because they understand the types testing FDA expects to see and it also helps FDA in that they can be consistent and make sure they're asking all of the companies that are submitting 510(k)s for the same kinds of information.
09:53:19 Q Can you tell us generally what categories of information the guidance document suggests that a manufacturer of an IVC filter should provide to FDA?
A So the kinds of information include different kinds of testing to address the risks. So we talked about
09:53:33 biocompatibility. Information about the mechanical integrity of the device. Can it withstand the forces that are being applied to it? So bench testing, mechanical testing.
The guidance talks about how to make sure that you've established that the device is sterile and maintains its
09:53:54 sterility.

09:53:55 It also talks about labeling. So FDA does review labeling as part of 510(k) submissions. This guidance document talks about what kind of information needs to be in the label for a intravascular filter.

09:54:11 MR. ROGERS: Can we go to page 5, please.

BY MR. ROGERS:

Q And, Dr. Tillman, are these some examples of the types of testing that FDA suggests to manufacturers that they would like to see before they submit an application for a 510(k) clearance of an IVC filter?

09:54:26 A Yes. There is biocompatibility and filter performance, for example.

MR. ROGERS: And can we go to the next page.

BY MR. ROGERS:

09:54:37 Q And what are the things that are listed here?

A So these are more specific examples about the types of mechanical testing that FDA expects to see for an IVC filter. So things like simulated deployment. So if when you introduce the filter into the patient, demonstrating you can, in fact, deploy the device into the patient's vessel. Things like clot-trapping ability or fracture and migration.

This is descriptions of the different kinds of testing that FDA expects to see in the submission.

Q And in your opinion as a regulatory professional, do you

09:55:20 think it's possible for a manufacturer of an IVC filter to

09:55:24 foresee and test for everything that might happen in the real world once these devices get into patients?

MR. LOPEZ: Objection, Your Honor. Disclosure.

MR. ROGERS: Page 95 of the report, Your Honor. It's

09:55:46 the second paragraph, second sentence.

MR. LOPEZ: I'll withdraw the objection, Your Honor.

THE COURT: All right.

BY MR. ROGERS:

Q Dr. Tillman, do you recall the question?

09:56:07 A Can you repeat it, please.

Q I'll be glad to.

In your opinion as a regulatory professional, do you think it is possible for a manufacturer of an IVC filter to foresee and test for everything that might happen in the real

09:56:21 world once those devices get into patients?

A No, I do not think it's possible to test for every possible scenario. I think it's only possible to test for reasonably foreseeable scenarios and the kinds of failures that we've seen in the past. But it's impossible to predict

09:56:38 everything that might happen.

Q Now, turning our attention back to the guidance document, does the document also identify known risks associated with IVC filters?

A Yes, it does.

09:56:52 MR. ROGERS: And can we go to page 7, please.

09:56:59 BY MR. ROGERS:

Q And down at the bottom of the page there, Dr. Tillman, is this where there's a discussion that picks up in the document about potential clinical risks?

09:57:08 A Yes.

Q All right.

MR. ROGERS: Can we go to the next page.

BY MR. ROGERS:

Q And, Dr. Tillman, is fracture listed as one of the

09:57:16 potential complications?

A Yes, it is.

MR. ROGERS: And can we go to the next page, please.

Down at the bottom where it says Filter Migration, is that one of the things that is identified by the FDA in the

09:57:30 guidance document as a potential risk?

A Yes, it is.

Q And next page, please. Dr. Tillman here is caval penetration and filter tilting. Are those also listed as known complications?

09:57:48 A Yes, they are.

MR. ROGERS: You can take that down, Scott. I'm going to switch it up a little bit.

BY MR. ROGERS:

Q Dr. Tillman, who were you retained by in this case?

09:58:10 A Nelson Mullins has retained me.

09:58:15 Q My law firm?
A Your law firm.
Q As part of that process, did you review documents that relate to the regulatory history of Bard's IVC filters?
09:58:23 A Yes, I have.
Q If there's certain documents you thought you wanted to see, did you request those?
A Absolutely.
Q And did you also do your own research that was available
09:58:34 to you publicly regard IVC filters?
A Yes, I did.
Q Did you spend a good deal of time on FDA's website looking at things that are available publicly regarding IVC filters?
A Yes, I did.
09:58:47 Q Did you review testing reports as part of your review of this material?
A Yes, I did.
Q And did you also review Bard's internal analyses they had done at various times about reports of complications?
09:59:00 MR. LOPEZ: Objection. This is leading.
THE COURT: I'm sorry?
MR. LOPEZ: Leading. I'm sorry.
THE COURT: Overruled.
THE WITNESS: Yes, I did.

09:59:07 BY MR. ROGERS:

Q And did you review charts of complications that Bard used to track the real-world performance of its devices?

A Yes, I did.

09:59:17 Q And did you review deposition testimony from Bard's employees?

A Yes.

Q And as part of your review, did you review all of the 510(k) applications that were submitted by Bard to FDA?

09:59:34 A Yes, I have reviewed them all.

Q And did you review all of the correspondence between FDA and Bard?

A Yes, I have.

Q Let me stop you there for a minute and let's talk a little

09:59:42 bit about something -- about a 510(k) application. Does it include something called a Truthful and Accuracy Statement?

A Yes, it does.

Q And can you describe for the jury what that is.

A So the regulations require companies to include a

09:59:59 statement in their 510(k), and I'm going to paraphrase it, that to the best of the person's knowledge all of the information in the 510(k) is truthful and accurate and that no material fact has been omitted.

So that is the Truthful and Accurate Statement.

10:00:17 It's required to be included in a 510(k) submission

10:00:21 and signed by the company that is submitting the 510(k).
Q Does the FDA have what I will call verbatim language it requires for 510(k) applications?
A So the regulations actually require companies to include
10:00:37 that statement exactly as it's written in the regulations. Unfortunately, sometimes companies make changes to it.
Q And in your review of some of the 510(k) applications for CR Bard, did the language that was included in the Truthful and Accuracy Statement always match the verbatim language that
10:00:57 FDA requires?
A No, it did not.
Q And in your experience is it uncommon for manufacturers to make adjustments to the truthful and accuracy language?
A Yes. My experience, both when I was at FDA and even still
10:01:10 today as a consultant, is that companies often think that that language is language that can be modified when in fact can't. It is supposed to be written exactly as it says in the regulation.
Q When did Bard submit a 510(k) application that did not use
10:01:30 the verbatim language the FDA requires for the Truthful and Accuracy Statement, did FDA clear those applications?
A Yes, they did.
Q And did you see any indication that FDA was unhappy because of the language of the Truthful and Accuracy
10:01:42 Statement?

10:01:45 A No, I did not see any indication FDA noticed the language was different.
Q When those applications that you reviewed that were submitted that used language that was not verbatim, was this
10:01:56 requirement of the Truthful and Accuracy Statement a relatively new requirement?
A I would say it was still relatively new to the medical device industry, yes.
Q And has FDA tightened up on that over the course of the
10:02:10 years?
A They have. Their new Refuse to Accept Guidance is pretty explicit it has to have the exact verbatim language in it.
Q All right. Dr. Tillman, let's talk about some of these clearances in 510(k) applications for some of the Bard
10:02:23 devices. And I want to start you off with our discussion with the G2 device. And what was the predicate device that was used in the G2 application in the 510(k) application?
A So the predicate for the G2 was Bard's Recovery.
Q And when the G2 510(k) application was submitted, was the
10:02:46 Recovery filter legally on the market?
A Yes, it was, to the best of my knowledge.
Q And would it be appropriate for the G2 application to use the Recovery filter as a predicate device?
A Yes. In fact, in my opinion, because the whole intent of
10:03:04 the G2 program was to improve the migration and fracture

10:03:08 resistance capabilities of the G2 over the Recovery, the Recovery was in fact the most appropriate device to use as the predicate.

Q And was there any requirement that Bard in this 510(k) application compare the G2 device to the predicate device for the Recovery filter, the Simon Nitinol filter?

A No. There's no requirement. A company is allowed to choose its own predicate device.

Q And I want to hopefully save the jury a little bit of time, but can you describe for us generally what the circumstances were when Bard made its application to the FDA for the G2 device.

A So when Bard came to FDA with the G2, they submitted it as a special 510(k), which is a type 510(k) that a company can make if they make modifications to the device that don't fundamentally affect its scientific performance or its fundamental scientific properties.

So Bard had the Recovery. They made modifications to improve fracture resistance and migration and they submitted a Special 510(k) to FDA for both the permanent and retrievable indications.

When that went into FDA, FDA looked at it and said we think we need some clinical data in order to support these changes. And so they said we can't clear the 510(k) for the retrievable indications without some clinical data, but we

10:04:46 can, we think, clear the 510(k) for the G2 for the permanent indications based on what you have.

So Bard submitted the 510(k) originally for retrievable and permanent as a Special. Then when they heard 10:05:00 from FDA they withdrew the retrievable indications. They said, okay, now we're going to just do the G2 for permanent. And as a result of that, then they had to submit additional testing information to support what we call a traditional 510(k) submission.

10:05:17 So it gets kind of complicated, but basically they submitted the traditional 510(k) for the G2 for the permanent indication.

Q Excuse me. As part of your work in this case, did you have access to internal documents that were created at FDA as 10:05:36 part of their evaluation process for the G2 filter?

A Yes, I did. When FDA reviews a 5 --

MR. LOPEZ: Excuse me.

THE COURT: Hold on.

MR. LOPEZ: This calls for yes or no answer, and I 10:05:47 want to approach the bench with respect to where she's going after -- with where she's going with the answer.

THE COURT: Then let's go ahead and do that now.

If you want to stand up, ladies and gentlemen, feel free.

10:05:58 (Bench conference as follows:)

10:06:13 MR. LOPEZ: Your Honor, she signed the G2 clearance letter. She's now talking about things that I can't cross-examine her on because the FDA doesn't allow me to cross-examine her on when she was at FDA. She signed off on the G2 510(k). Now she's going in and describing what happened at FDA. That's in violation of the FDA rules, first of all, for her to give that kind --

THE COURT: Let me interrupt you for just a minute.

I think the question you asked was whether she had access to internal FDA documents.

MR. ROGERS: Correct, Your Honor.

THE COURT: Do you know what's being referred to with internal FDA documents?

MR. LOPEZ: It almost doesn't matter because she's going to give testimony from her perspective as having been there and been involved in that process. So I can't cross-examine her on that. I was not able to take her deposition on it because she's the one who was involved in the process.

10:07:06 THE COURT: I understand.

MR. ROGERS: I have no intention of going into that.

THE COURT: What are you going to do with these internal FDA documents?

MR. ROGERS: Well, these are internal FDA review memos where they lay out their reason for clearing a device.

10:07:18 What I'm going to do, what I would like to do, is enter them into evidence and ask her if she's reviewed them and kind of move on. That's all I'm planning to do.

THE COURT: Are you going to ask her to give any

10:07:27 information she acquired while within FDA?

MR. ROGERS: Not anything extensive, Your Honor.

THE COURT: Well, anything at all.

MR. ROGERS: Well, I mean, just this is what it is and kind of move on. I mean, I'd love to do it but she's

10:07:41 going to be constrained by her report and she doesn't say a lot.

THE COURT: So you want to move into evidence the internal FDA memos --

MR. ROGERS: Correct. Yes.

10:07:49 THE COURT: -- ask her if she's reviewed them, she'll say yes, and then you'll move on to a new area?

MR. ROGERS: Yes.

THE COURT: You're not going to ask her anything about her memos or her review of them?

10:08:00 MR. ROGERS: Well, I mean I'll probably just ask a general question --

THE COURT: Such as?

MR. ROGERS: Does this reflect FDA's thinking at the time. Something along those lines.

10:08:07 THE COURT: Okay.

10:08:08 MR. LOPEZ: I'd love to cross-examine her on that from the standpoint of her role there, what she did, what information she had, whether or not this was factored into her when she signed that letter. I can't do that. I mean, her
10:08:22 role --

THE COURT: But if what -- are you going to oppose the admission of the internal FDA review documents?

MR. LOPEZ: Well, yes. We always object to those.

THE COURT: What will be the basis --

10:08:36 MR. LOPEZ: Hearsay and we don't have the opportunity to cross-examine.

THE COURT: What is your response on hearsay?

MR. ROGERS: On hearsay, Your Honor, it's going to be 803, the public records.

10:08:45 THE COURT: (8).

MR. ROGERS: (8). Yes, sir. I can't remember the subsection, but I can get it if we need it.

THE COURT: What is your response on 803(8)?

MR. LOPEZ: Well, I mean they're still hearsay.

10:08:56 THE COURT: But if they satisfy 803(8) they can come in.

MR. LOPEZ: If they don't, how do they? I mean I don't know how they satisfy 803(8).

THE COURT: So 803(8) applies if a record or
10:09:22 statement of a public office sets out the office's activities.

10:09:27 These are disjunctive. You don't have to satisfy all of them. You can leave it there. Which section are you going to rely on?

MR. ROGERS: 803(8)(a)(1).

10:09:38 THE COURT: So the argument is these are a record of a public office that sets out the office's activities. What is your response.

MR. LOPEZ: My response is it's 403. I cannot --

THE COURT: That's not a hearsay objection. Let's

10:09:50 stay on hearsay.

MR. LOPEZ: Okay. I'm sorry. These are -- what he's saying are the internal thinking or whatever, I can't remember what he said --

THE COURT: He said they're internal review memos.

10:10:07 MR. LOPEZ: Right.

THE COURT: And you've made a hearsay objection.

MR. LOPEZ: Right.

THE COURT: My question to you is, why doesn't 803(8)(a)(1) solve the hearsay problem?

10:10:24 MR. LOPEZ: Well, I mean -- Mr. O'Connor -- what's the guarantee of trustworthiness? The issue is -- that's what's so unfair about FDA documents. We don't have -- and why there's a mini trial about this stuff. We cannot -- we can do nothing to determine trustworthiness of any of this

10:10:44 stuff because we can't cross-examine any of the people

10:10:47 involved. I mean that's why it's a 403 issue.

THE COURT: You're now looking at 803(8)(b); is that right?

MR. LOPEZ: Okay. Yes.

10:10:55 THE COURT: And for that to apply, the source of the information or other circumstances must indicate a lack of trustworthiness.

What indicates a lack of trustworthiness?

MR. LOPEZ: I mean just -- I can't -- again, the

10:11:11 reason I can't answer that question is because we don't have an opportunity to cross-examine anybody on those documents to determine whether or not they're trustworthy, how they're formed, who did it, was it done by, you know, an electrical engineer, was it done by a medical doctor --

10:11:27 THE COURT: I understand your point.

MR. LOPEZ: -- things that would be important for cross.

THE COURT: Have you seen any case law which holds that internal government documents that cannot be the subject

10:11:36 of a deposition are inadmissible under Rule 803(8)(a) because of a lack of trustworthiness?

MR. LOPEZ: No, I haven't.

THE COURT: Wouldn't that be true of every government document where you can't go depose the government people about

10:11:51 the document?

10:11:52 MR. LOPEZ: Well, I mean, probably. But --

THE COURT: Okay. In the absence of any case law, my conclusion is that -- I'm assuming these are publicly available internal memos. You didn't -- these weren't

10:12:03 spirited out of the FDA by this lady?

MR. ROGERS: No, sir. They were obtained via a FOIA request.

MS. REED ZAIC: In the Cook litigation.

THE COURT: What did you say?

10:12:16 MS. REED ZAIC: FOIA request that came in in the Cook --

THE COURT: Okay. They're available through FOIA requests. I can't conclude a document obtained by a FOIA request fails to satisfy 803(8)(a)(1). It appears to set

10:12:26 forth the office's activities. And the source or other circumstances do not indicate a lack of trustworthiness.

Now, you have a different objection you made a moment ago.

MR. LOPEZ: You said that would apply to all of it.

10:12:39 This is the decision-making body. If this is a memo in another case involving some other department where there's a decision making going on, then, again, the unfairness is us not having an opportunity to challenge what's in those documents by being able to cross-examine people at FDA.

10:12:58 THE COURT: Do you have a copy of the document?

10:13:00 MR. LOPEZ: I don't.

MR. ROGERS: I do, Your Honor. It's in the box over there.

THE COURT: Tell me what it says.

10:13:05 MR. ROGERS: Your Honor, it is an official document, it's signed by the person, and it's a form that they file where they go through and put their reasons and all the things they analyzed based on their review of the 510(k) application.

THE COURT: So it's specific to --

10:13:24 MR. ROGERS: Specific to the G2 filter.

THE COURT: The G2. What is the document number?

MR. ROGERS: There's actually two, because if we get through this I was going to go to another. But it's 6064 and 6061.

10:13:35 THE COURT: Hold on just a minute.

MR. ROGERS: Sure.

THE COURT: I was just checking. Both 6064 and 6061 were admitted in the Jones trial.

MR. ROGERS: Yes, sir.

10:14:28 MR. LOPEZ: I don't know where he's going. It talks about activities. I mean, these are conclusions, these are findings, these are --

THE COURT: You've seen these documents. They've been in evidence in this courtroom in a previous trial. So

10:14:38 there's no mystery as to what the documents are.

10:14:43 MR. LOPEZ: I don't know what one he's talking about.

THE COURT: He just said 6064 and 6061.

MR. LOPEZ: I need to know whether he's going beyond activities. Is he going to ask her to give an opinion whether

10:14:53 or not this is --

THE COURT: My understanding from what Mr. Rogers said -- and you need to tell me if this is right, Mr. Rogers -- you're going to move the document into evidence, you are going to ask if she reviewed it, and then you said you

10:15:08 intended to ask a general question such as does this document set forth the agency's reasons, and then you're going to move on and not ask her --

MR. ROGERS: I'm not going to ask her to render an opinion or anything of that nature.

10:15:22 THE COURT: All right.

Are there other objections, Mr. Lopez?

MR. LOPEZ: No.

THE COURT: I'll wait until you move them into evidence to admit them.

10:15:29 MR. ROGERS: Okay. Thank you, Your Honor.

(Bench conference concludes.)

THE COURT: Thank you, ladies and gentlemen.

Go ahead, Mr. Rogers.

MR. ROGERS: Thank you, Your Honor.

10:15:54 BY MR. ROGERS:

Q Dr. Tillman, before we took our sidebar we were talking about whether you had the opportunity to review some internal documents from FDA. Do you recall that?

10:16:01 A Yes, I did.

Q And did you have a chance to do that?

A Yes, I did.

Q And did those documents that you included from FDA include memos from FDA that were created regarding their review of the

10:16:17 G2 application?

A Yes, I did. Yes, they did.

MR. ROGERS: And can we pull up Exhibit 6064, please.

BY MR. ROGERS:

Q And, Dr. Tillman, do you have that on your screen?

10:16:31 A Yes, I do.

Q And is that one of the internal documents that you reviewed from FDA?

A Yes, it is.

MR. ROGERS: And, Your Honor, at this time I move

10:16:38 this document into evidence.

MR. LOPEZ: I'd like to see the second page.

My only objection is there's some redactions on here, Your Honor. I don't see what they are. If we're going to move this into evidence I'd like to have an opportunity to see

10:17:11 what's been redacted in the event I want that included.

10:17:15 THE COURT: Well, let's go ahead and leave that subject to your conferring. If you want to raise it again, I'll be happy to consider it.

MR. LOPEZ: Thank you, your honor.

10:17:21 THE COURT: I'll admit it subject to plaintiffs' ability to review the redaction.

(Exhibit 6064 admitted.)

MR. LOPEZ: Thank you, Your Honor.

MR. ROGERS: Thank you, Your Honor. May we display?

10:17:29 THE COURT: You may.

BY MR. ROGERS:

Q Dr. Tillman, in your review of this document, was this one of internal documents you reviewed that set forth FDA's analysis of the 510(k) application for the G2 filter?

10:17:43 A Yes, it is.

MR. ROGERS: All right, we can take that down, please.

And would you pull up Exhibit 6061.

And, Scott, why don't you go ahead and scroll through

10:17:59 the pages.

BY MR. ROGERS:

Q And, Dr. Tillman, is this another document that you reviewed that was an internal memo from FDA regarding their analysis of the 510(k) application for the G2 filter?

10:18:16 A Yes, it is. Yes, I did review it.

10:18:19 MR. ROGERS: And, Your Honor, I move this into evidence.

MR. LOPEZ: Your Honor, same objections as we discussed at sidebar, plus there are some redactions on this 10:18:28 one.

THE COURT: All right. 6061 is admitted subject to plaintiffs' opportunity to review the redactions.

(Exhibit 6061 admitted.)

BY MR. ROGERS:

10:18:35 Q Dr. Tillman --

MR. ROGERS: May we display the document, please?

THE COURT: Yes.

BY MR. ROGERS:

Q So, Dr. Tillman, does this document set forth several 10:18:43 pages --

MR. ROGERS: And can you scroll to the next page, please, Scott.

BY MR. ROGERS:

Q Does it set forth several pages of FDA's analysis and 10:18:50 reasoning behind their ultimate clearance of the G2 filter?

A Yes, it does.

MR. ROGERS: All right. Can you scroll again, please, Scott.

And one more time.

10:19:08 Thank you.

BY MR. ROGERS:

Q And so, Dr. Tillman, did the FDA ultimately clear the G2 device as a permanent filter?

A Yes, they did.

Q Do you recall approximately when that was?

A Somewhere in the August of 2005 time.

Q And in your experience as a regulatory professional, if the FDA was concerned about the issues related to the IFU that accompanied the G2 filter or in general the safety and efficacy of the G2 filter, would it have cleared the device?

A No. In my experience, if FDA had had any concerns they would not have cleared the device.

Q All right. Dr. Tillman, let's kind of move forward a little bit in time. And after the FDA had cleared the G2 filter as a permanent device, did FDA also conduct a clinical trial regarding the G2 filter?

A Bard conducted the clinical trial. Yes.

Q That trial was known as what?

A That was the EVEREST trial.

Q And the jury has heard the term IDE or investigational device exemption. Can you describe for us again what that is.

A So an IDE is a submission that a company makes to the FDA when they want to do a clinical study of a device that's not yet approved. And so -- or cleared. So the purpose is to make sure that human subjects are appropriately protected

10:20:37 before FDA allows the device to be studied.
Q And can a manufacturer conduct a clinical trial involving human subjects if it does not obtain an IDE first?
A Not -- not for an IVC filter, no.
10:20:51 Q And when a manufacturer develops a clinical study for an implantable device like an IVC filter, to what extent is FDA involved in that process?
A So FDA is often very much involved. There's often a lot of back and forth between FDA and the sponsor in developing
10:21:10 the study.
Q And what are the sponsor, or in this case Bard's, obligations regarding the study in regard to communicating with FDA?
A So the -- Bard has to submit an application that includes
10:21:24 all of the testing that shows the device is safe to be used in human subjects. And once FDA approves the IDE and the study begins, the company also has to submit periodic reports to FDA about the study progress.
Q All right.
10:21:39 MR. ROGERS: Can we pull up Exhibit 5340, please.
And, Your Honor, I believe this document is in evidence.
THE COURT: Yes.
MR. ROGERS: May we display?
10:21:51 THE COURT: Yes.

10:21:52 BY MR. ROGERS:

Q So, Dr. Tillman, for the benefit of the jury, can you tell us what this document is, please.

A So I believe this is the traditional 510(k) submission to 10:22:01 add the retrievable indications to the G2 filter.

Q And when a manufacturer submits a 510(k) application to FDA, must it include the labeling or IFU that will accompany the product?

A Yes, that is a required part of any 510(k) submission.

10:22:21 Q And as part of FDA's review of the 510(k) application, does the FDA review the labeling or the content that's contained in the IFU?

A Yes. FDA most definitely reviews the labeling.

Q And what is FDA's role in reviewing that labeling?

10:22:37 A So FDA's role is to make sure that the labeling is consistent with guidance, if there is guidance, and to make sure that the labeling appropriately presents the risk information about the product.

Q And if FDA believes the labeling or the IFU that the 10:22:53 manufacturer submits is deficient, what can FDA do?

A If FDA finds any deficiencies in the labeling or any other part of the submission, they will contact the submitter and ask them to make changes or express their concerns.

Q And in your review of the 510(k) application for the G2 as 10:23:15 a retrievable device, did Bard provide FDA the data regarding

10:23:22 complications that were seen in the EVEREST study?
A Yes, they provided the full data about all of the complications.
Q And did Bard provide EVEREST -- excuse me. Did Bard
10:23:33 provide to FDA the data from the EVEREST study that related to reports of tilt and caudal migration?
A Yes, they did.
Q And did they also provide data regarding perforation that was seen during that study?
10:23:45 A Yes, they did.
Q And did FDA ultimately clear the 510(k) application for the G2 filter as a retrievable filter?
A Yes, they did.
Q All right.
10:23:57 MR. ROGERS: You can take that down, please, Scott.
BY MR. ROGERS:
Q All right. Let's again move forward in time, Dr. Tillman, and let's talk now about the G2X or the -- the G2 Express filter. Can you tell the jury what that filter did as far as
10:24:12 changing the design of the filter.
A So the purpose of the G2X was to add -- to modify the hook on the top of the filter to enable the filter to be retrieved by a snare. So it was a modification to change the way the filter could be retrieved.
10:24:31 Q And once that hook was added, what was the original name

10:24:34 that that filter was known by?
A I'm not sure what you're referring to, I'm sorry.
Q I'm sorry, I'm just trying to make clear that this -- this filter with the hook on it at some point was known as both the
10:24:54 G2X and G2 Express.
A Oh, I'm sorry. Yes. G2X and G2 Express are the same. And I may refer to them interchangeably.
Q Okay. If we see a document with reference to G2 Express, is that a G2X filter?
10:25:09 A That is my understanding.
Q Okay. Thank you.
MR. ROGERS: Can we pull up Exhibit 5373, please.
BY MR. ROGERS:
Q And, Dr. Tillman, can you tell us what this is, please.
10:25:20 A So this is the Special 510(k) submission that Bard submitted to make that modification we just discussed. So this is the 510(k) for the G2 Express.
MR. ROGERS: And, Your Honor, I do not believe this is in evidence and I move it in, please.
10:25:36 MR. LOPEZ: No objection, Your Honor.
THE COURT: Admitted.
(Exhibit 5373 admitted.)
MR. ROGERS: May we display?
THE COURT: You may.

10:25:42 BY MR. ROGERS:

Q Dr. Tillman, what we see here, is this the cover page for the application to the FDA for 510(k) clearance for the G2 Express or G2X filter?

10:25:54 A Yes, it is.

Q What is the date of that document?

A March 7th, 2008.

Q And have you reviewed this application in its entirety?

A Yes, I have.

10:26:04 Q And did FDA have any questions or concerns about the modification that was made in adding the hook to the filter?

A I believe FDA had some questions about the biocompatibility for the change in the design.

Q And do you recall if FDA sent any correspondence to Bard?

10:26:26 A Yes. FDA sent a letter to Bard that asked for additional information about the biocompatibility and Bard was then -- responded to that request.

Q And what was the difference between the hook and the rest of the device?

10:26:42 A So the hook was actually electro -- mechanically electropolished, and so FDA, when they looked at that change, they said how did you determine that by electropolishing it you didn't change the material properties and that that might have affected whether that material was compatible with the

10:27:02 human tissue. Biocompatibility. So FDA asked Bard about

10:27:08 that.
Q And did Bard respond to FDA?
A Yes, they did.
Q And was FDA ultimately satisfied with the response Bard
10:27:14 gave?
A Yes, they were.
Q Did FDA clear the G2X or G2 Express filter?
A Yes, they did.
Q All right.
10:27:24 And again, Dr. Tillman, let's continue to move forward in history and talk about the Eclipse filter.
MR. ROGERS: And can we pull up Exhibit 5272, please.
BY MR. ROGERS:
Q Dr. Tillman, what is this document?
10:27:40 A So this is the Special 510(k) that Bard submitted to the FDA for the Eclipse filter.
MR. ROGERS: And, Your Honor, I move this document into evidence.
MR. LOPEZ: No objection, Your Honor.
10:27:50 THE COURT: Admitted.
(Exhibit 5272 admitted.)
MR. ROGERS: May we display?
THE COURT: You may.
BY MR. ROGERS:
10:27:55 Q And first of all, just to orient us from a time

10:27:58 standpoint, what's the date of this document?
A November 23rd, 2008.
Q And --
A 2009. 2009.
10:28:07 Q Thank you for that correction.
And above the date it says Special 510(k) submission.
Can you describe for the jury what is a Special 510(k).
A So a Special 510(k) is a type of a 510(k) that a company
10:28:24 can submit if they've already got a regular 510(k).
So Bard already had a 510(k) that was cleared for the G2X. And if they make a modification to their own device and they don't change the indications and they don't change the fundamental scientific technology, they can submit a Special
10:28:43 510(k) where, instead of having to provide a detailed explanation for substantial equivalence and providing all of the test reports, instead, what they have to do is they have to basically describe what are the new risks that this change could cause? How have we mitigated the risks? And then they
10:29:04 have to summarize the testing, but they don't have to actually provide the actual test reports.
And FDA reviews a Special 510(k) more quickly than a traditional 510(k), and so that's why the program exists, to allow incremental changes to be reviewed more quickly.
10:29:23 Q And what was the technological difference between the G2X

10:29:26 filter and the Eclipse filter?

A So on the G2X, if you recall, I mentioned that the hook was electropolished. For the Eclipse, all of the wire was electropolished.

10:29:40 MR. ROGERS: All right. Can we go to page 35 of this document, please.

And can we pull out that section says call Risk Analysis?

THE COURT: We'll deal with that after the break. 10:29:49 We'll break until 10:45. We'll see you at that time.

(Recess taken from 10:30 to 10:47. Proceedings resumed in open court outside the presence of the jury.)

THE COURT: Please be seated.

Counsel, you wanted to raise a matter before the jury 10:47:27 comes back in?

MR. LOPEZ: Yes, Your Honor. We looked at 6064, which is the FDA -- the FDA letter that came in July 26, 2005, while the Recovery was still on the market, and they redacted without our agreement, "population have led to death." They 10:47:58 took out "have led to death" out of that document. Twice, I think. Isn't there a second spot here?

Then on page 4, "There have been reports of complications" redacted, "including death, associated with the use of the Recovery filter," et cetera.

10:48:23 Anyway, they took death out of both of these FOIA

10:48:27 documents. Pretty significant redaction.

THE COURT: What are you requesting?

MR. LOPEZ: I'd like you to have this testimony and these documents stricken from the record because --

10:48:40 THE COURT: What testimony stricken?

MR. LOPEZ: The testimony about these two documents, 6064 and 6061. Another redaction in 6061.

THE COURT: We admitted them subject to your reviewing the redactions. Are you saying you don't want them

10:48:55 unredacted, you want everything stricken?

MR. LOPEZ: No, I'd like them unredacted.

THE COURT: All right, is that your request, then? That's different than striking them from the record.

MR. LOPEZ: Yes, unredacted.

10:49:05 THE COURT: Okay.

Response?

MR. ROGERS: Your Honor, it's my understanding those were the redactions that were agreed to in the Jones case. And it was also my understanding that as a starting point for

10:49:15 this trial we were going to use the documents as they were ultimately redacted in the Jones case so that we would not have this last-minute problem that we ran into with the Jones trial where we were trying to get all the things redacted so they could go to the jury room.

10:49:31 And so the documents I'm using have got the Jones

10:49:34 redactions.

And I'll also point out very briefly yesterday Mr. O'Connor was examining Mr. Carr -- or when I was putting in documents with Mr. Carr and Ms. O'Quinn he kept saying 10:49:47 "subject to redactions." I mean, they wanted these redactions in the documents. So I think we've got an inconsistent position over here and I think, frankly, it doesn't make any sense not to start with the redactions from the Jones case.

THE COURT: Well, were those redactions in the Jones 10:50:03 case, Mr. Lopez?

MR. LOPEZ: I don't know.

THE COURT: Well, you should know. What does your side say? You agreed to all of that in the Jones case.

MR. LOPEZ: I don't know what happened in the Jones 10:50:11 case. All I know is this is the Hyde case.

THE COURT: Well, but did the parties have an agreement that the documents would be subject to the same redactions in the Jones case as a starting point?

MS. SMITH: I think what happened in these documents 10:50:25 is these exceed the scope of what the actual redactions were supposed to be in the Jones case.

THE COURT: Were they redacted in the Jones case?

MS. SMITH: I don't know --

THE COURT: Well, figure that out and then we'll talk 10:50:36 about the issue.

10:50:37 Counsel, you've got to be on top of this stuff. The "I don't know what happened in the Jones case" isn't helpful at all to my resolving these issues.

MR. LOPEZ: Well, Your Honor, when I get notice of
10:50:46 documents that they're going to use, I go to the document. I don't go to the Jones document, I go to the document --

THE COURT: But if you've agreed that you're going to start with redactions in the Jones case --

MR. LOPEZ: I never agreed with that. That's never
10:51:00 been an agreement ever.

THE COURT: You said they agreed to that, Mr. Rogers.

MR. ROGERS: Your Honor, that was my understanding. Ms. Helm may know more about that than I do.

THE COURT: Tell me what you think the agreement is.

10:51:10 MS. HELM: Your Honor, we addressed it in the pretrial order and we proposed it, and the list of the -- the exhibits that have been exchanged on an ongoing basis throughout the course of the litigation, we've always been sending them the redacted version as it was admitted in Jones.

10:51:27 THE COURT: And what did you say in the pretrial order about it?

MS. HELM: We said -- I've lost my -- I'm sorry. Oh. I'm sorry, Your Honor. In the pretrial order we limited it to the Recovery migrations deaths. It's on page 69 on page 3.
10:51:44 I'm sorry. Page 69, paragraph 3, line 10. Our proposal was

10:51:52 limited to Recovery migration deaths.

But the exchange going back has been the redacted documents and the documents that we've been operating on based on their insistence of the redactions have been those admitted 10:52:07 in Jones.

THE COURT: All right. Well --

MS. SMITH: Can I clarify something --

MR. LOPEZ: We have one more --

THE COURT: Let's get to the heart of this. We have 10:52:14 the jury waiting.

Whatever is your reasons for suggesting we should not redact those portions of this document?

MR. LOPEZ: Well, I mean, it deals with her testimony that FDA was well informed about what was -- from the company 10:52:30 about what was going on with the Recovery device when in fact they were not. I can't cross-examine now on that issue because the most important thing that FDA probably would have wanted to know about were the number of times Recovery filter was causing deaths.

10:52:45 THE COURT: Well, but -- I'm not understanding that. This is an FDA document where FDA is referring to the deaths. So that doesn't support your argument that the FDA didn't know about the deaths.

MR. LOPEZ: Well, I know, but how -- it says "Adverse 10:53:01 events in this patient population have led to death." What

10:53:05 the does that mean? How much did the FDA really know about the Recovery filter as it's contemplating the G2 filter?

THE COURT: Well, Mr. Lopez, my understanding is you want the jury to see that the FDA made reference to death in

10:53:25 this document. That's why you want it unredacted. Correct?

MR. LOPEZ: Yes. But then I want to be able to cross-examine someone with it, too, with that issue in it.

THE COURT: Sounds like you want to open a door and walk through it.

10:53:44 MR. LOPEZ: Well, you know, I mean, I can't. I don't have time to do it --

THE COURT: So what do we do? I'm getting inconsistent signals --

MR. LOPEZ: They used a document on her direct

10:53:54 examination that was not agreed to. Two documents. This one, I have no idea they redacted "The sponsor states the filter's implantation and removal stimulates worse case conditions for evaluation of the vessel grossly and histopathologically." What does that have to do with deaths? I mean, that's also a

10:54:13 very significant redaction.

I'd like them stricken from the record and her testimony about them stricken.

THE COURT: Okay, that's the relief you're requesting?

10:54:22 MR. LOPEZ: I'm sorry?

10:54:22 THE COURT: That's the relief you're requesting?

MR. LOPEZ: Yes, Your Honor.

THE COURT: Okay.

Your response?

10:54:25 MR. ROGERS: Your Honor, I would need to confirm the transcript. I don't believe I asked this witness one question about the Recovery filter other than to say it was the predicate device for the G2.

I did not go over any safety issues with her with the

10:54:40 Recovery filter. Did not go over the regulatory history with the Recovery filter. And I just cannot understand how this is some door-opening situation.

THE COURT: And what is the reason for the second redaction that Mr. Lopez read?

10:54:55 MR. ROGERS: This is not -- I don't know this for sure, but I have what I think is a solid guess. When we were admitting the documents --

THE COURT: Solid guess.

MR. ROGERS: I'm sorry, Your Honor.

10:55:05 THE COURT: I'll remember that phrase.

MR. ROGERS: When we were going through the redaction process with the Jones documents, Plaintiffs' counsel was very insistent that they wanted to remove all hearsay within hearsay in the FDA record. And I will bet a lot of money that

10:55:21 that statement that says "the sponsor states," et cetera, was

10:55:25 redacted because they insisted on it coming out because it was hearsay within hearsay.

So these are redactions that were agreed to in Jones and I just don't understand why we're talking about this.

10:55:35 THE COURT: All right.

Well, on the question of whether these will be stricken from the record, what I want is confirmation that these were redactions made in the Jones case. So look at the Jones exhibits.

10:55:51 If they were redactions made in the Jones case, it would have been by agreement of the parties because I didn't dictate redactions in any of the documents.

If parties agreed to these redactions in the Jones case I'm not going to strike the document from the record

10:56:07 because they included the same redactions as the Jones case. I don't see a basis for doing that. So I'm going to deny the request to strike the documents from the record if these redactions were in the Jones case. Sounds like you need to do some work to confirm that. Do that and let me know when you

10:56:24 get to it.

While we were on break we got a note from Juror Number 6. I'll read it to you. It says, "Please help me understand," quote, "housekeeping," close quote "that results in evidence being admitted that has not been discussed in the

10:56:39 course of the trial. At least not obviously to me. Thank

10:56:43 you."

I think this must be a reference to you this morning, Mr. O'Connor, saying we have a housekeeping matter we want to move into evidence that one exhibit. And the juror is not
10:56:58 understanding why that's happening when it wasn't discussed with a witness.

That's seems to me to be the intent of the note.

MR. O'CONNOR: That was an exhibit, and perhaps it can be clarified, from the Jason Greer deposition. It should
10:57:17 have come in but it didn't. And I'll let Ms. Zaic --

MS. REED ZAIC: It wasn't on the summary we normally read prior to --

THE COURT: For Greer?

MS. REED ZAIC: It was for Greer. And it was
10:57:28 discussed, but it wasn't on the list and erroneously we did not move it in at the time --

THE COURT: What I would suggest is I just explain that at the time the jury comes in, that it was Greer document that didn't come into evidence, as a housekeeping matter we
10:57:40 got it into evidence.

We'll do a better job in the future of explaining what a document is when we're doing that. Is that fair?

MR. ROGERS: Yes, Your Honor.

MR. O'CONNOR: Yes, Your Honor.

10:57:50 THE COURT: Okay. Let's get the jury back in.

10:57:54

(The jury entered the courtroom at 10:58.)

THE COURT: Thank you. Please be seated.

Thanks for your patience, ladies and gentlemen. We had a legal issue to work through, and rather than have you

10:58:56 sit in here while we did it at sidebar, we just took care of it before you returned.

Also, I received a note from Juror Number 6 asking about a housekeeping matter that results in evidence being admitted that wasn't discussed.

10:59:12 I assume that was a reference to the statement this morning, as a housekeeping matter we want to admit an exhibit and I admitted it and nothing more was said. Or yesterday we'd done that.

The one that came in this morning was an exhibit that

10:59:25 should have been moved into evidence in the Jason Greer video excerpt and it just was omitted from the list. So the housekeeping matter was to formally get it into evidence. But that document that came in this morning was related to the Jason Greer deposition.

10:59:46 When we do this in the future, we'll do a better job of saying where it's coming from so it just isn't a number out of space like I allowed this morning.

Okay. Mr. Rogers, you may proceed.

MR. ROGERS: Thank you, Your Honor.

10:59:59 Scott, can you pull back up Exhibit 5272, please.

11:00:03 BY MR. ROGERS:

Q And, Dr. Tillman, since we've had our break, I do want to just ask you briefly, so the document we were looking at was what?

11:00:11 A So this is the Special 510(k) for the Eclipse filter.

Q All right.

MR. ROGERS: Would you mind pulling out the Risk Analysis section, please.

Maybe we display, Your Honor?

11:00:24 THE COURT: Yes.

BY MR. ROGERS:

Q Okay. So, Dr. Tillman, can you tell us, if you would, what this information is that is contained in the 510(k) application that is being conveyed to FDA.

11:00:39 A So as I mentioned, when you make a modification to a device, you have to consider how that change impacts the risk of the device. So what this says is that Bard conducted a type of a risk analysis called a design failure modes and effects analysis in order to evaluate the risks associated

11:01:01 with the change that they made.

And so they've identified what the risks were and then, based on what those risks were, they identified how they were going to mitigate them and what verification and validation activities they were going to do. So how they were

11:01:15 going to test the device to show that the risks had been

11:01:19 mitigated.
Q And did Bard show FDA that information how it was testing the device?
A Yes. There was a summary of the testing that was done to
11:01:28 mitigate the risks.
Q In your opinion, was the presentation of the information that was contained in the Special 510(k) for the Eclipse consistent with what FDA would want to see for a Special 510(k)?
11:01:41 A Yes. The information is consistent with how Special 510(k)s are put together.
Q Okay.
MR. ROGERS: Can you take that down and pull up Exhibit 5588, please.
11:01:53 And, Your Honor, I move this into evidence.
MR. LOPEZ: No objection, Your Honor.
THE COURT: Admitted.
(Exhibit 5588 admitted.)
MR. ROGERS: May we display?
11:02:09 THE COURT: You may.
BY MR. ROGERS:
Q So, Dr. Tillman, again, just to orient us, can you see the document there on your screen?
A Yes, I do.
11:02:14 Q And is this a letter that FDA wrote to Bard in response to

the 510(k) application for the Eclipse?

A Yes. This is what we call an additional information request.

MR. ROGERS: Scott, would you mind pulling out the second paragraph, please.

BY MR. ROGERS:

Q So, Dr. Tillman, what is FDA asking of Bard in this particular paragraph?

A So FDA is saying that they have recognized that Bard has conducted corrosion testing, cyclic fatigue testing, and arm fatigue testing, but that FDA says that electropolishing the device may affect their strength and that Bard needs to do radial force testing, migration and clot testing, and filter tensile strength testing.

MR. ROGERS: Okay. Can you take that down and pull up Exhibit 5486.

BY MR. ROGERS:

Q And, Dr. Tillman, have you reviewed this document?

A Yes, I have.

Q Is this the responses that Bard gave to FDA to their questions about the Eclipse filter?

A Yes, it is.

MR. ROGERS: Your Honor, I move this into evidence.

MR. LOPEZ: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 5486 admitted.)

MR. ROGERS: May we display?

THE COURT: You may.

MR. ROGERS: And if you would, Scott, can you turn to page 7 of that document, please.

BY MR. ROGERS:

Q And so, Dr. Tillman, in your review of this, did Bard respond to FDA specifically about the testing that it was asking about?

A Yes, they did.

Q And if we looked there at the bottom of the --

MR. ROGERS: Yeah. Thank you, Scott. At the bottom of the page there.

BY MR. ROGERS:

Q Did FDA report the results of the testing that FDA was requesting?

A Yes. So Bard reported the results of the testing for the radial force testing in this paragraph.

MR. ROGERS: And can we go to the second page, please. Or the next page.

BY MR. ROGERS:

Q And did Bard also report the results of the migration/clot trapping testing?

A Yes, they did.

Q And if we go to the next page, did Bard also report the

11:04:19 filter tensile strength testing to FDA?
A Yes, they did.
Q After Bard submitted these responses to the FDA's specific questions, did FDA ask Bard for any additional testing?
11:04:33 A No, they did not.
Q And did FDA ask any additional questions of Bard regarding the content of the IFU?
A No, I do not believe that they did, no.
Q And did the FDA ultimately clear the Eclipse filter?
11:04:49 A Yes, they did.
Q And if FDA had been concerned about potential of fracture with the Eclipse filter, would Bard have cleared the device?
A So FDA would not have cleared the device if they were concern about potentials for fracture.
11:05:06 Q And, Dr. Tillman, are you aware of an additional 510(k) application that got submitted by Bard to FDA for the Eclipse filter?
A Yes, I am.
MR. ROGERS: And can we pull up Exhibit 5586, please.
11:05:21 And, Your Honor, I move this into evidence.
MR. LOPEZ: No objection, Your Honor.
THE COURT: Admitted.
(Exhibit 5586 admitted.)
MR. ROGERS: May we display?
11:05:31 THE COURT: You may.

11:05:31 BY MR. ROGERS:

Q Dr. Tillman, can you tell the jury what this is?

A Yes. So this is another Special 510(k) submission and the purpose of this one was to add a patient brochure and an

11:05:42 implant card that Bard had developed in order to provided additional information for patients.

Q And in your opinion as a regulatory professional, was Bard required to submit a 510(k) application for the patient brochure and implant card?

11:05:59 A No. It's my opinion that they actually did not need to submit a 510(k) for this change.

Q And so if they were not required to do that, what would be the reason why that would occur?

A So it's my understanding that the only reason to do this

11:06:15 would be to obtain FDA's feedback on the information and make sure FDA was comfortable with the information.

Q All right.

MR. ROGERS: Let's go to page 78 and 80 of that, please. And can you put them both up, Scott? And if you

11:06:37 can't, don't worry about -- oh. Okay. Great. Thank you.

BY MR. ROGERS:

Q So, Dr. Tillman, what do we see there on -- we've got them sort of in backwards order. That's okay, we'll go that way. On the left-hand part of the screen, what is that that we see

11:06:52 there?

11:06:53 A That is an implant card that is often developed for devices that are permanent implants and it's given to patients and they carry it around in their wallet so that they can let people know what devices they have.

11:07:06 Q And is that something that was part of this submission to the FDA for the Eclipse filter brochure and implant card?

A Yes, it was.

Q Okay.

MR. ROGERS: And can you take down the left-hand

11:07:18 screen, please.

BY MR. ROGERS:

Q And then, Dr. Tillman, what are we seeing here?

A So this is, I believe, the patient brochure that Bard developed for the Eclipse filter.

11:07:32 Q Did FDA ultimately clear this patient brochure?

A Yes. So this brochure was submitted in the Special 510(k) which FDA cleared.

Q To your knowledge, was there any questions FDA had about this patient brochure?

11:07:47 A I believe that there was one question and that Bard made the change that FDA requested and then FDA cleared the 510(k) submission.

Q Okay. Thank you.

MR. ROGERS: Scott, you can take that down.

11:07:59 BY MR. ROGERS:

Q Dr. Tillman, let's talk a little bit about IFUs. And specifically I want to ask you about the IFU's that accompany the G2X filter and the Eclipse filter. And based on your

11:08:18 experience as a regulatory professional, do you have an opinion as to whether or not Bard provided to doctors in those two IFUs appropriate information about their products?

A Yes. It's my opinion that the IFUs include risk information that was consistent with FDA's guidance document

11:08:40 and also consistent with sort of current industry practice for IFUs for these kinds of devices.

Q If FDA had wanted changes in the language or additional information included in those IFUs, could FDA have asked for that?

11:08:54 A Yes, they could, and they certainly did throughout the sort of history of these filter submissions. We've seen several instances where FDA has asked for changes to the filter labeling.

Q All right. And continuing on in this, I guess line of

11:09:10 questioning about IFU's, would it be, in your opinion as a regulatory professional, appropriate for a manufacturer like Bard to provide information in an IFU that would compare its rates of complications with another manufacturer's rates of complications?

11:09:28 A So in my opinion the only time it would be appropriate to

11:09:32 do that would be if you had done actually a clinical study where you had -- you had done a study where you had studied both devices and you were comparing those rates. I do not believe it would be appropriate to include that kind of rate
11:09:46 information based on, for example, the publicly available MDR adverse event data.

Q Okay. And jury has heard from time to time during this trial the MAUDE database. Can you tell us what MAUDE stands for?

11:10:00 A So the MAUDE database is the database that is publicly available that includes adverse events that are reported to FDA by healthcare facilities and by manufacturers for medical devices. So it's basically the database of adverse events.

Q All right.

11:10:18 MR. ROGERS: And can we pull up Exhibit 7795, please.

And, Your Honor, I would move this into evidence, please.

MR. LOPEZ: Can you -- can I ask counsel to just describe it. I can't really read it. If he tells me what I
11:10:56 think is, I'm not going to object to it.

THE COURT: Why don't you have the witness say what it is.

MR. ROGERS: Sure. I'll be glad to.

BY MR. ROGERS:

11:11:02 Q Dr. Tillman, do you recognize what is on the screen?

A Yes, I do.

Q Can you tell us what that is, please.

A Yes. So as I mentioned, the MAUDE database is actually searchable. So there's actually a website where you can go and you can type in search terms and you can search FDA's database for information about adverse events.

And so what we're looking at right now is a -- is a screen shot showing what you would see if you were using sort of an old browser, it looks like. The formatting is a little bizarre. But what you would see if you went to FDA's website and you were to actually go to search the MAUDE database.

Q Thank you, Doctor. This isn't the version I was looking for either, but it's what I got.

MR. ROGERS: Your Honor, I move this into evidence.

MR. LOPEZ: My only objection is this is not a document that is on her reliance list or included in her report.

THE COURT: Is this in her report, Mr.--

MR. ROGERS: Yes, it is, Your Honor. And if you go to page 86 of the report, above number 2.

THE COURT: Did you say above number 2?

MR. ROGERS: I did, Your Honor.

THE COURT: You mean the paragraph above --

MR. ROGERS: I'm sorry. The paragraph that is numbered number 2, which is at the bottom of the page, and the

11:12:27 sentence just above that.

THE COURT: Well, that's not a discussion of this exhibit; right? It may have a sentence from it, but it's not a discussion of the exhibit generally.

11:12:44 MR. ROGERS: All right, Your Honor. May I pull out that one sentence?

THE COURT: Well, I mean, there's no objection, I assume, based on the report, to her recounting what's in that sentence in her report; is that right, Mr. Lopez?

11:12:57 MR. LOPEZ: Yeah, the sentence in her report's fine. My only concern is this is a 2018 web shot.

THE COURT: All right. So the objection is sustained with the exception of the sentence quoted in her report.

MR. ROGERS: Thank you.

11:13:08 Scott, if you would -- excuse me. Can you pull out the sentence that reads -- starts "MDR data alone."

BY MR. ROGERS:

Q All right. Dr. Tillman, what does the FDA state on this website in this sentence, please?

11:13:32 A FDA states that "MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time" --

MR. LOPEZ: I'm sorry, Your Honor, this is going beyond what is in her report. I ask it be taken -- it's not

11:13:46 shown.

11:13:47 THE COURT: It's not being shown.

MR. LOPEZ: There's a sentence -- it stops at "between devices."

THE COURT: That's what she was just reading.

11:13:55 MR. LOPEZ: I know, but if you look at the screen, it goes beyond that.

THE COURT: So it's the first sentence.

BY MR. ROGERS:

Q Dr. Tillman, would you mind reading the first sentence, please.

11:14:05 A "MDR data alone cannot be use to establish rates of events, evaluate a change in event rates over time, or compare event rates between devices."

Q Thank you.

11:14:16 MR. ROGERS: You can take that down, please.

BY MR. ROGERS:

Q As part of your review of materials in this case, did you look at IFUs for other IVC filter manufacturers?

A Yes, I did.

11:14:29 MR. ROGERS: Can we pull up Exhibit 7787, please.

And can you go to the next page, please, Scott.

And next page.

Next page.

BY MR. ROGERS:

11:14:43 Q Okay. So, Dr. Tillman, can you describe for the record

11:14:45 what this document is.

MR. LOPEZ: Your Honor, disclosure in the report.

MR. ROGERS: Your Honor, it's discussed on page 79. Or it's listed on page 79 of her report.

11:14:55 THE COURT: All right. Where's the discussion of it in the report?

MR. ROGERS: The document is identified on page 79, and then there is a discussion about other manufacturers' IFU's on page 84 of the report.

11:15:24 THE COURT: And where is the document identified on page 79?

MR. ROGERS: Do you see the table there?

THE COURT: I do.

MR. ROGERS: It is the second one -- actually, the

11:15:33 first entry under the table.

THE COURT: Instructions for use?

MR. ROGERS: Yes, Your Honor.

THE COURT: Okay. Then the discussion is on page 84?

MR. ROGERS: Yes, Your Honor. The first sentence.

11:16:00 THE COURT: I think you can ask her questions that elicit the sentence statement at the top of page 84, but that seems to be as far as she goes in the discussion.

MR. ROGERS: Your Honor, I would like to move this into evidence.

11:16:17 THE COURT: Objection?

11:16:18 MR. LOPEZ: Yes, Your Honor.

THE COURT: Based on?

MR. LOPEZ: Hearsay and not -- also not relevant to this case and it's not included, any part of this other than

11:16:27 what he just stated, included in her report.

THE COURT: What is the response on hearsay?

MR. ROGERS: Your Honor, I'm not moving it in for truth of the matter but to offer evidence of industry standards.

11:16:40 THE COURT: What's your response on that, Mr. Lopez?

MR. LOPEZ: Well, only to the extent what is included in her report. I mean, he wants to get in the entire document when that is not something that is included.

THE COURT: Well, but the exhibit isn't subject to a

11:16:52 report limitation. Exhibits can be admitted if they're relevant. What can she say about it is limited to her report. So the fact -- so that isn't an objection to the admissibility. What I heard you object on was hearsay and relevancy.

11:17:08 MR. LOPEZ: Yes, Your Honor.

THE COURT: Are there other objections?

MR. LOPEZ: No, Your Honor.

THE COURT: All right. I think it's relevant and I'm going to admit it with an instruction to the jury, which is

11:17:17 Exhibit 7787 is not being admitted for the truth of anything

11:17:22 stated in the document. It's not being admitted to prove what's in the document. Only as an example of what was in documents like this in the industry. That's the only basis upon which it is being admitted.

11:17:36 And with that instruction I will admit 7787.

(Exhibit 7787 admitted.)

MR. ROGERS: May we display?

THE COURT: You may.

MR. ROGERS: Scott, would you mind going back to page 11:17:47 1.

BY MR. ROGERS:

Q Dr. Tillman, again for the benefit of the jury can you describe what this document is?

A Yes. This is the instructions for use or the IFU for the 11:17:56 Cordis OptEase vena cava filter.

Q And did you review this as part of your work in this case?

A Yes, I did.

Q And Dr. Tillman, are you aware of any medical device that includes adverse event data based on post-marketing 11:18:12 information such as the MAUDE database in its IFU?

A No, I'm not aware of any device that includes that information in its IFU.

Q And would that be consistent with this IFU that is on the screen?

11:18:24 A Yes, it would be.

11:18:26 MR. ROGERS: All right. Thank you, Scott. You can take that down.

And can you pull up Exhibit 7787. I'm sorry, excuse me. 7771.

11:18:38 BY MR. ROGERS:

Q And Dr. Tillman, can you identify this document?

A Yes. This is the IFU for another vena cava filter, the B. Braun VenaTech.

Q And did you review this document in the course of your

11:18:53 work in this case?

A Yes, I did.

MR. ROGERS: Your Honor, I move this into evidence.

MR. LOPEZ: No objection, Your Honor.

THE COURT: Admitted.

09:25:03 (Exhibit 7771 admitted.)

BY MR. ROGERS:

Q So, Dr. Tillman, if you would, explain again for the jury what we're seeing.

I don't think I asked to display. May I display,

11:19:14 Your Honor?

THE COURT: You may.

MR. ROGERS: Thank you.

THE WITNESS: So once again, this is the IFU for the B. Braun VenaTech IVC filter.

11:19:24 BY MR. ROGERS:

Q And as part of this, your work, did you review what this particular IFU includes regarding complications that they warn of?

11:19:33 A Yes, I did.

Q And did you see anything in this IFU that would indicate that this particular IFU provides information that would provide any sort of comparative analysis of the complications with this filter to any other filter based on MAUDE data?

11:19:50 A No. I did not see that there was any evidence of that information being included in this IFU.

Q Okay. Thank you.

MR. ROGERS: You can pull that down, Scott.

BY MR. ROGERS:

11:20:00 Q And, Dr. Tillman, just to wrap up, in your opinion as an expert in FDA regulatory affairs, did the G2X and Eclipse IFUs contain risk information that were consistent with industry standards that existed at the time?

A Yes, they did.

11:20:21 Q And in submitting 510(k) applications to the FDA and responding to FDA's questions, did you see any occasion where you believed, in your opinion, Bard had not appropriately disclose information to the FDA as part of the 510(k) process?

A I did not see any evidence of that, no.

11:20:39 Q And are all of the opinions you've offered here today,

have they all been given to a reasonable degree of certainty as an expert in the field of regulatory affairs?

A Yes, they have.

MR. ROGERS: Thank you, Dr. Tillman, I don't have any further questions at this time.

THE COURT: Cross-examination.

C R O S S - E X A M I N A T I O N

BY MR. LOPEZ:

Q Morning, Dr. Tillman?

A Morning.

Q How are you?

A I'm fine, thank you.

Q Okay. As part of your charge in this case as an expert, were you asked to look at the risk -- any risk analysis that was done by Bard in comparing the safety and performance of any of the Bard devices to the Simon Nitinol filter or any of its competitive devices?

A As I sit here today, I'm not sure. I saw a risk analysis that directly -- what I would call a risk analysis that made that comparison.

Q And Dr. Asch -- you know who Dr. Asch is; right?

A Yes, I do.

Q And you were not provided, as part of your doing your report in this case and rendering an opinion, you were not provided with Dr. Asch's 2016 deposition that was played in

this trial; true?
A I don't believe I requested to be -- to review that deposition, no.
Q Well, what happened, you had discussions with counsel about the fact there was a 2016 deposition and you asked, is there really any reason for me to read his deposition, and they told you there was no reason for you to read that deposition; true?
MR. ROGERS: Objection, Your Honor. Statement contains hearsay and it's also 403.
THE COURT: Sustained on hearsay grounds.
MR. LOPEZ: Okay.
BY MR. LOPEZ:
Q You did ask about that deposition; true?
A I'm not sure what you mean when you say I asked about the deposition --
Q Well, let me put it this way. You discussed earlier that you had conversation with the defense counsel about what you should look at and what you shouldn't look at, and one of the things they told you didn't need to look at was the 2016 deposition of Dr. Asch; true?
A So I wouldn't characterize it as them saying I didn't need to look at it.
MR. LOPEZ: Can I have the deposition, 2017 deposition, page 62, please. Line 9.

BY MR. LOPEZ:

Q Do you remember your deposition was taken just about a year ago?

A Yes, I remember this deposition.

Q The question was, "And the same would hold true for Dr. Murray Asch. You read Dr. Asch's deposition that was taken in January of 2011, but you knew there was a deposition taken in 2016; right?"

"Answer: I would have seen it on the list."

"Question: And you had discussions with counsel about the fact that there was a 2016 deposition and you asked, 'Is there really any reason for me to read his 2016 deposition?'And they said no. Is that essentially what happened?"

"Answer: Essentially. It may not have been those exact words, but, yes."

Did I read that testimony correctly?

A Yes, I believe that's correct.

Q Okay. Now, there's never been a determination by FDA that any of the Bard filters is safe and effective; true?

A That is correct.

Q And would you agree that federal regulations require all information in a 510(k) be truthful, accurate, and no material fact to be omitted; correct?

A That is correct.

11:24:41 Q Part of your charge was not to perform an audit of Bard's internal documents see if there was important material information that they withheld from FDA; true?
A That is correct.
11:24:57 Q So you can only form your opinions based on the information that you provided that were -- that was provided to you by the lawyers; true?
A And the information that I obtained through publicly available sources. Yes.
11:25:11 Q Would you agree that companies have a responsibility to make their products continue to be safe and effective independent of any FDA action or inaction?
A I think that companies -- yes, I would agree companies need to make sure their products are safe and effective as
11:25:25 they can be.
Q And you also agree that the overall study objective of EVEREST was the safety of removal of the filter; true?
A And also evaluation of adverse events. Yes.
Q And it was not intended to look at the long-term impact of
11:25:43 permanent implantation of the G2 filter; true?
A I believe that's correct.
Q And I think you previously testified that the Asch pilot study was also not intended to look at long-term impact of the permanent implantation of the Recovery filter; true?
11:25:58 A Yes. The Asch study was intended to look at the

retrievability of the Recovery filter.

Q What was the clinical experience in the open market prior to the EVEREST study completion? Do you know?

A I don't know what you're asking.

Q Well, I want to know whether or not before the EVEREST study was completed whether Bard provided you with any clinical information about how the G2 device was actually performing in the open market. Did they provide you with that?

A So before the EVEREST study was completed the G2 filter was only cleared for use as a permanent filter. And so are you asking me whether I was aware of what the adverse event data were associated with the G2?

Q No. Any of the clinical performance of the device. Whether -- what type of things were being reported about some of the complications and risks and seriousness of some of those complications. Did you look at that material?

A Yes. I certainly do recall looking at material about adverse events and experience Bard was having with the G2 filter while the EVEREST study was under way and some of the communications they had with FDA about that.

Q But part of your charge in this case as an expert was not to render an opinion as to whether or not Bard should have been doing something with respect to that information they were receiving and whether or not the device should be

redesigned for those purposes; true.

In other words, you weren't evaluating the design of the G2 filter or any of their filters to determine whether or not for safety reasons it should be redesigned. True?

A My role in this is to give opinions about FDA regulatory matters and whether Bard's actions were consistent with FDA's regulatory requirements.

Q And not whether or not the devices were appropriately and safely designed; true? Is that true?

A Only in the context of whether or not Bard's actions were consistent with the FDA's requirements.

Q Dr. Tillman, is it important to understand the long-term performance of a device before it's launch?

A I think it's important -- I think it's important to have information that will inform what we expect the long-term performance to be before it's launched.

Q And you agree a company like Bard doesn't need the FDA to tell it to continue a study nor to do a long-term safety study.

A If it is appropriate for Bard to do such a study, then they don't need FDA to tell them to do a study, they should do it.

Q And would you agree that if there were important scientific questions that still need to be answered, then a study should be done?

11:28:46 A I think that studies -- if there are important questions that need to be answered, then, yes, study should be done.
Q Do you know what a Type A or Type B fracture is?
A I do.
11:28:54 Q What is a Type A fracture?
A So my understanding is a Type A fracture is a fracture of a filter where there is -- where it embolizes, part of the filter embolizes I believe to the heart, but I couldn't be sure about that. But it involves an embolic event versus just
11:29:11 a fracture.
Q You looked at some IFUs and you talked about that. Did you ever look at the internal Bard data to determine the reporting rate differences between the Bard filters and any other filters as relates to Type A fractures? Yes or no?
11:29:31 A I'm not sure what you mean by a reporting rate difference because that's not a term that is usually used.
Q Well, you know that Bard did internal analysis and did statistical analysis between their device and the Simon Nitinol filter and other devices; true?
11:29:47 A I know that over the years Bard looked at -- compared its adverse event rates to rates of other devices based on MAUDE data. Yes, I'm aware of that.
Q Now, Dr. Tillman, if a company knows that it has design deficiencies, that is not only something that they ought to
11:30:05 share with doctors, but the company actually needs to do

something about that. Wouldn't you agree?

A I would agree that if a company has identified that there's problems with the design of the device, that the company needs to take some kind of action to -- at the very least to investigate it, absolutely.

Q I think you previously testified --

MR. LOPEZ: Let's look at the 2017 deposition. Line 17, page 189.

Page 189 on the 2017 deposition.

BY MR. LOPEZ:

Q Do you see where I am, Dr. Tillman? And you stated there that "I think if a company knows it has, quote, design deficiencies, then not only is that something physicians ought to know, but the company actually needs to do something about that.

"Question. They ought to stop selling it?"

"Answer: If they have design deficiencies."

That was your answer just a year ago; true?

A I would say that still is my answer. If they actually do find there is a problem with the device, then I think they should stop selling it.

Q Do you agree Dr. Tillman, when you design a device and you have a risk, ideally the best thing to do to mitigate the risk is to design around it? You design the device so that the risk goes away; true?

11:31:32 A Ideally that is absolutely the case. Unfortunately, that is not always possible.

Q And you also agree that adverse event data can produce a signal and investigating that signal may lead a company to

11:31:44 determine that it needs to make design changes; true?

A Absolutely.

Q Just want to get one document, Exhibit 696. Ask you to identify it.

Do you recognize that document?

11:32:06 A Yes. This is a GAO report.

Q You were at FDA at that time?

A I was.

Q This document describes in some detail while you were there some of the shortcomings of the FDA because of its

11:32:18 resources, et cetera; true?

A This is a GAO report where they investigated problems -- or shortcomings, as they found, with FDA's review process, yes.

Q And you had an opportunity to review this report prior to

11:32:33 it being finalized; true?

A I had the opportunity to review it and identify any errors in fact. Yes.

MR. LOPEZ: I'd like to offer, Your Honor, Exhibit 696 into evidence at this time and just show the -- publish

11:32:47 the cover page to the jury.

MR. ROGERS: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 696 admitted.)

THE COURT: You may I publish.

BY MR. LOPEZ:

Q There were other similar reports throughout the course of the last 20 years where the GAO investigates FDA and has made some findings about the FDA, because of its resources and lack of funding, is incapable sometimes of carrying out its mission; true?

A I think that is probably an oversimplification, but there have certainly been a number of GAO reports of FDA, I would agree with that.

Q Can we agree companies like FDA have to follow FDA's regulations even if the FDA doesn't tell them to do so?

THE COURT: I think you want to rephrase that question.

THE WITNESS: Yeah.

BY MR. LOPEZ:

Q Do we agree companies like Bard have to follow FDA's regulations even if FDA doesn't tell them to?

A Absolutely.

Q And you've never been provided information about Dr. Kandarpa's comments at least with respect to the EVEREST study; true?

11:33:54 A I believe I may have seen some of Dr. Kandarpa's comments, but not -- not in the context of before I prepared this report.

Q Bottom line is the company is an entity that designs, 11:34:06 profits, markets, sells medical devices like IVC filters, and they're the ones responsible for the safety and effectiveness of the device; true?

A I absolutely think medical device companies are responsible for their devices. Absolutely.

11:34:22 MR. LOPEZ: Thank you, Your Honor. No further.

THE COURT: Redirect.

MR. ROGERS: Very briefly.

R E D I R E C T E X A M I N A T I O N

BY MR. ROGERS:

11:34:34 Q Dr. Tillman, in your work in this case, were you provided all of the material that you requested?

A Absolutely.

Q And were you also provided with lists of every deposition that was taken as part of this litigation?

11:34:48 A I was, and it was a rather long list.

Q And were you able to go through that list and make determinations about which deposition you thought it would be appropriate for you, as a regulatory professional to review?

A Yes, I was.

11:35:00 Q And did you receive every deposition that you requested?

A Every one I asked for I received.
Q And, Doctor, can you give the jury some idea about how much material you have received.
A So I have an entire external hard drive that is just dedicated to this project.
Q And approximately how much data is on that external hard drive?
A A lot. If it were paper it would be kind of scary. That's one of the reasons it's all electronic.
Q And, Doctor, while you were at FDA for 17 years, did you believe the FDA appropriately carried out its duties to examine medical devices and make appropriate decisions for the healthcare of the American people?
MR. LOPEZ: Objection, Your Honor. Leading and suggestive.
THE COURT: Sustained on leading.
MR. ROGERS: All right. Thank you.
BY MR. ROGERS:
Q Dr. Tillman, how would you describe the job you think FDA did while you were at FDA for 17 years?
A I think the people that are there are incredibly passionate about what they do. I think, yes, in the past they haven't always had the resources they would have liked to have had and so sometimes it was hard for them to do their jobs. But I think everybody that's there is trying to do the best

they can for public health because, after all, we all end up using medical devices at one point in time.

MR. ROGERS: Thank you, Dr. Tillman. I don't have any further questions.

THE COURT: All right. You can step down.

Defense counsel.

MS. HELM: At this time we call Dr. Scott Trerotola by video deposition.

Dr. Scott Trerotola is a board certified radiologist with a specialty in interventional radiology. He maintains a clinical practice in interventional radiology at the Hospital of the University of Pennsylvania where he has been chief of the radiology department since 2001.

He graduated from the University of Pennsylvania Medical School in 1986 and has been implanting IVC filters since the 1990s.

He has been retrieving optional filters since they first came on the market in the early 2000s. He has also served as a consultant for Bard in the past.

Your Honor --

THE COURT: Hold on just a minute.

JUROR: Can we ask for the name to be spelled. Last name.

THE COURT: Would you spell the name, please.

MS. HELM: I apologize. I should have done that,

11:37:51 Your Honor. It is hard to pronounce.

It's T-R-E-R-O-T-O-L-A. Trerotola.

THE COURT: All right. You may play the deposition.

(Video testimony of Dr. Scott Trerotola started.)Hold on
11:38:15 just a minute, Counsel. Let's pause it for a minute.

We need to put the mic down by the speaker again, please.

MR. O'CONNOR: Is it coming out of here?

THE COURT: Actually, we can hear it from a speaker
11:38:32 over here.

Why don't we restart it and see if it's better.

Would you please state your name for the record please.

(Video testimony of Dr. Scott Trerotola played.)

11:55:12 MS. HELM: Your Honor, at this time we call Dr. Paul Briant.

THE COURTROOM DEPUTY: Sir, if you'll please come forward, stand right there, raise your right hand.

Could you State your name and spell your last name.

11:55:54 THE WITNESS: Paul Briant, B-R-I-A-N-T.

MS. HELM: Thank you, Your Honor. May I proceed?

THE COURT: You may.

PAUL BRIAN Ph.D,

called as a witness herein, after having been first duly sworn
11:56:05 or affirmed, was examined and testified as follows:

11:56:05

D I R E C T E X A M I N A T I O N

BY MS. HELM:

Q Dr. Briant, would you please introduce yourself to the jury.

11:56:39

A Sure. My name is Paul Briant.

Q What is your profession?

A I'm a mechanical engineer and I work at Exponent Failure Analysis Associates.

Q And where is Exponent -- the office of Exponent Failure

11:56:50

Analysis that you work?

A We're in Menlo Park, California.

Q Would you please tell the jury your educational background that resulted in you being a mechanical engineer.

A Sure. So I did my undergraduate work at Washington

11:57:02

University in St. Louis where I got my bachelors of science in mechanical engineering and graduated summa cum laude, then I went on to Stanford University where I got my masters and Ph.D also in mechanical engineering.

Q You said you graduated summa cum laude from Washington

11:57:20

University in St. Louis?

A Yes, I did.

Q What does that mean? Is that the highest level --

A Correct, that's the highest you can receive.

Q Did you get straight As?

11:57:28

A Almost.

11:57:28 Q Did you get a B?
A I did. I got one B. It was in Greek pathology.
Q And, again, would you explain to the jury, you went on and got your masters and your Ph.D in mechanical engineering.
11:57:42 What was the topic of your Ph.D research?
A Sure. So I studied tissue mechanics. So understanding how biological tissues will respond to mechanical forces that are applied to them. In particular, I was looking at knee cartilage and understanding causes for knee arthritis.
11:58:01 Q And in what year was your dissertation approved and you were awarded your Ph.D?
A In 2008.
Q Are you a licensed engineer?
A Yes, I'm a professional engineer.
11:58:11 Q Licensed in the state of California?
A Yes.
Q And you said you work for Exponent Failure Analysis Associates. What does that company do?
A So we're a technical consulting firm. So we provide
11:58:23 engineering and scientific consulting services.
Q And how long have you been with Exponent?
A I've been there for ten years.
Q And at the Exponent offices in Menlo Park, California, are you the only Ph.D?
11:58:36 A No. We have about 150 engineers there.

11:58:42 Q And why do companies come to Exponent to have you perform analysis for them?

A So they come for a variety of reasons. They may not have the expertise or the resources to do an analysis in house. 11:58:55 But most importantly we're often an independent reviewer to analyze their devices.

Q And what types of entities do you perform analysis for? You personally.

A Sure. So I do a lot of work in medical devices. I also 11:59:08 do a lot of work in electronics industry. My work focuses on solid mechanics, so understanding the stresses and strains inside of various devices and structures.

Q The jury's heard in this case that the IVC filters --

THE COURT: Let me interrupt you. We're going to 11:59:26 break at this point.

MS. HELM: Thank you, Your Honor.

THE COURT: Members of the jury, we'll resume at 1 o'clock and we'll excuse you at this time.

(The jury exited the courtroom at 12:00.)

11:59:56 THE COURT: You can step down, Dr. Briant. Thank you.

Counsel, be seated for just a minute. I assume you'd like your time now?

MR. O'CONNOR: Please, Your Honor.

12:00:05 MS. HELM: Your Honor, I can get you the allocation.

12:00:07 THE COURT: Yeah, would you get me the DeFord and Trerotola allocations.

MS. HELM: Dr. DeFord was 8 minutes for the plaintiff and 13 minutes for the defense.

12:00:22 Dr. Trerotola was 9 minutes for the plaintiff and 7 minutes for the defendant.

THE COURT: Okay. Give me just a minute.

Okay, Counsel, as of the lunch hour plaintiffs have used 31 hours and 6 minutes. Defendants have used 22 hours

12:02:43 and 58 minutes. That includes the allocations of the deposition time.

I did not charge to either side the 15 minutes we spent while the jury was out. But I did allocate 5 minutes of the earlier sidebar to plaintiffs. So that's included. Plus

12:03:01 the deposition allocations.

We'll see you at 1 o'clock.

MR. LOPEZ: Thanks.

MR. ROGERS: Thank you, Your Honor.

MS. HELM: Your Honor, before you leave the bench,

12:03:38 yesterday at the end of the day, plaintiffs had used 31 hours and 1 minute.

THE COURT: Right.

MS. HELM: Today you said they've used 31 hours and 6 minutes.

12:03:48 THE COURT: I said 31 hours and 36 minutes.

12:03:51 MR. ROGERS: I'm sorry. I misunderstood.

THE COURT: Wait a minute. Did I misspeak? It was 31 hours and 36 minutes.

MS. REED ZAIC: I heard the same thing as Ms. Helm.

12:04:01 THE COURT: Okay, then I misspoke. There was 35 total minutes allocated today. 31 hours 36 minutes.

MS. REED ZAIC: I prefer yours. Thank you, Kate.

(End of a.m. session transcript.)

* * * * *

C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 3rd day of October, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter